RESEARCH METHODS IN

U N A N I MEDICINE

As per the Syllabus by NCISM for BUMS

2nd Edition

By

Dr. Syed Badshah Mohiuddin(BUMS,MD)

This book is dedicated to the students of Unani medicine who wish to put their efforts for the betterment of the system

Preface to First Edition

Allah deserves all the praise, peace and blessings be upon the Holy Prophet. As I started preparing for the first year exams of MD-Unani, I began to focus more on research methodology. There was something about the subject that never killed my zeal to study more and more. When I referred various books, journals and materials I had the idea of preparing notes that can help me in getting good grades in the exams and can also help me in performing the research project for partial completion of MD-Unani.

After preparing the notes, my intentions started to grew. It started to cook in my mind that I must be shaping the notes I prepared into a brief guide that can help research scholars of unani system of medicine. After a hard work of five months, I was ready to present before everyone what was cooking in my mind.

I have prepared this guide keeping in mind the syllabus for MD-Unani provided by Central Council for Indian Medicine (CCIM). This brief guide has been named as “Research methods in unani medicine” instead of research methodology because I feel this guide is more about getting acquainted with the research methods rather than the methodology of the research.

In some chapters, beside the headings or sub-headings the details of some of the question papers in which the topic was asked has been mentioned to help the readers understand the significance of the topic with respect to the exams.

If any of my colleagues, teachers or any other scholars, professors find any kind of error in the book please be kind enough to inform me.

Dr. Syed Badshah Mohiuddin
December, 2019

Ch.No	Table of Contents	Pg No
1	**Introduction to Research**	**1-27**
	What is research?	3
	Health Research	3-4
	Research methods and Research Methodology	5
	Objectives of Research	6-10
	Objectives of Research in Health Sciences	6-7
	Objectives of Research in Unani Medicine	7-9
	Comparitive Persepective	9-10
	Scope of Research in Health Sciences and Unani Medicine	11-16
	Scope of Research in Health Sciences	11-12
	Scope of Research in Unani Medicine	13-15
	Emerging Areas in Scope	15
	Comparative Scope Table	15-16
	Historical Development of Contemporary Research	17-21
	Evidence of Research in Classical Unani Literature	22-27
2	**Evidence-Based Medicine (EBM) and Integrative Medicine**	**28-40**
	Evidence-Based Medicine (EBM)	28-30
	Integrative Medicine (IM)	30
	Current Status of Unani Medicine Research	31-32
	Current Status of Integrative Medicine Research	32
	Future Directions in Unani and Integrative Medicine Research	33-34
	Research Works of CCRUM in Unani Medicine Since Its Inception	34-40
3	**Types of Research**	41-49
	Basic, Applied, and Translational Research	41-44
	Qualitative, Quantitative, and Mixed Methods Research	45-49
4	**Research Design**	50-
	Observational Research	50-63
	Descriptive Study	52-56

	Case Reports	52-53
	Case Series	53-55
	Community diagnosis or needs assessment	55
	Epidemiological description of disease occurrence	55
	Descriptive Cross-sectional studies or Prevalence studies	55
	Ecological descriptive studies:	56
	Analytical Research	57-63
	Case Control Study	57-60
	Cohort Study	60-63
	Experimental/Interventional Research	64-80
	Animal Experiment	64
	Human Experiment	65
	Randomized Controlled Trial	65-71
	Preclinical Design in Unani Medicine	72-76
	In Situ Studies in Unani Research	72-73
	In Silico Methods: Digital Simulations and Unani Medicine	73
	In Vivo Preclinical Studies in Unani Medicine	73-74
	In Vitro Approaches: Cell and Tissue-Based Research	74-75
	Integrative Preclinical Design: Strengths and Challenges in Unani Medicine	75-76
	What is Clinical Research?	77-80
	Quasi experimental design	80-81
	Meta-Analysis and Systematic Review	82-86
	Non-conventional designs	87-90
	Black Box Design	87
	N-1 Design (N-of-1 Trial)	87-88
	Whole System Research	88
	Flexible-Dose Design	88-89
5	**Research Ethics**	**91-119**
	Ethics in research related to Humans and Animals	91-92
	Pharmacovigilance Program for Unani and ASU&H Drugs	93-95
	ICMR medical guidelines	96-97

	ICH-GCP (International Council for Harmonisation–Good Clinical Practice) guidelines	98-100
	GCP unani guidelines	101-104
	Demonstration of ethical principles through case scenario	104-105
	CPCSEA guidelines	106-107
	Institutional Human Ethics Committee (IHEC/IEC)	108-110
	Institutional Animal Ethics Committee (IAEC)	111-113
	Ethical issues specific to Unani medicine research through different case scenarios	114-116
	Publication ethics	117-119
6	**Research process**	**120-170**
	Process for selection of topic	120-121
	Literature search in a medical database	122
	Systematic Literature Review	123-124
	Sources in Literary Research	125-129
	Research Problem	130-131
	Hypothesis	132-136
	Steps in Unani Hypothesis Formulation	135-136
	Aims & Objectives of Research	137-138
	Procedure to conduct research in Unani medicine	139
	Tools in research	140-143
	The Interview Method	140-141
	Questionnaire	142-147
	Scales	148-151
	Standard Terminologies in Unani Medicine	152
	Methodology in Unani Medicine Research	153-154
	Factors affecting the research results	155-157
	Bias	158-159
	Errors in Research	160-162
	Analysis and interpretation of results in research	163-165
	Research conclusions	166-167
	Reporting of Research	168-169
7	**Databases and Portals of Unani Medicine**	**170-177**
	DHARA (Digital Helpline for Ayurveda Research	170-171

	Articles)	
	AYUSH Research Portal	171
	UGC-CARE (Consortium for Academic and Research Ethics)	171-172
	PubMed	172
	Scopus	173
	NAMASTE Portal	173-174
	A-HMIS (Ayush Hospital Management Information System)	174
	Other Relevant Portals and Resources	174-175
8	**Guidelines for Reporting Research: Overview and Key Types**	**178-193**
	PRISMA guidelines for conducting reviews	181-183
	STROBE Guidelines: Strengthening the Reporting of Observational Studies in Epidemiology	184-186
	CONSORT Guidelines	187-189
	ARRIVE Guidelines	190-191
	CARE Guidelines	192-193
9	**Intellectual Property Rights (IPR), Patents, and TKDL in Unani Medicine**	**194-200**
10	**Research Critique**	**201-222**
	Critically Evaluating a Research Article in Health and Unani Research	202-204
	Bibliometrics	205-207
	Reference formats	208-221
	Predatory Journals	222
	Quality Journals	222
	Computer Programs used in research	**223-228**
	SPSS	223-226
	Minitab	227-228

Chapter 1.
Introduction to Research

Allah deserves all the praise; it is He who knows all that is seen and unseen. Peace and blessings on the best creation, the beloved Prophet who did not learn from any creation. The Almighty Allah quotes in the Quran as: “And above every possessor of knowledge is (also) one possessing greater knowledge” (12:76). At some other point in the Quran the Almighty quotes as “So if you yourselves do not know (anything) then ask the people of remembrance” (16:43). Syeduna Anas ibn Malik (May Allah be pleased with him) narrated that the Messenger of Allah (Peace and Blessings be upon Him) said: “When you pass by the gardens of the Paradise, then feast”, they said: “What are the garden of the paradise?” He said: “The gatherings of Knowledge”. Holy Prophet (Peace and Blessings be on Him) said: “Seek knowledge even if you have to go to China”. Holy Prophet (Peace and Blessings be on Him) said: “Whoever sets out from his home to gain knowledge for the sake of Allah is in the way of Allah until he returns”.

In the light of the above narrations, it can be summed up that the Islam encourages Muslims to search for the knowledge, attain and practice it. In fact, the search for knowledge is regarded as an act of worship. It is never mentioned in any narration that there is any specific age for starting to learn neither there is an end to it. This consolidates that the search for knowledge is a continuous and life long process. The Quran mentions: “and Allah is great knowing”. There are many other verses in which Allah is described as possessor of great and ultimate knowledge and for human beings it is mentioned as “There is nothing for the man except that which he strives for”

It is believed that the perfection is only possessed by the Almighty while there is always a room for improvement in the human beings. A sense of perfection breeds ego and satisfaction while the hunger for improvement breeds sophistication.

A researcher needs to understand and accept that there is always a possibility of sophistication in the field of study because inherent in the definition of research is the search for new knowledge. The information in any subject is ever evolving. The information which was considered as the peak of human knowledge a century ago is being

deemed as outdated today while information regarded as “the supreme” today might become outdated tomorrow.

Also, if it is believed that there is no scope of further study in a particular subject then it leads to stagnation in the subject. The stagnation is often considered as the death of any subject, while an alive subject is the one with the most updated knowledge.

As the time passes the trends among the people changes and so does their requirements. Unfortunately, the possessors of the knowledge of the unani medicine have failed to adapt to the changing trends. The unani system of medicine was burdened due to the consequences of this failure so much so that its back is almost broken now. The disinterest shown by a large number of unani practitioners in unani is an evidence of that.

What is research?

In an attempt to play a hand at sophistication lay people often use sentences like “I did research in this subject”. The words “studying”, “learning” however suits well to their activity rather than the term research. This highlights that the research is a systematic process of careful and continuous enquiry rather than a superficial learning or getting acquainted with existing information. From this point of view, the research can be defined as a systematic process of exhaustive search for knowledge. In research either new information is discovered or it is verified or the existing information is interpreted in a new way. The concept of introducing something new in the subject is always the primary goal of the research.

There may or may not be a pre-defined specific purpose of the research. If the search for knowledge is meant for a specific purpose i.e. finding a solution to a problem then it is called applied research whereas if there is no specific purpose of research and research is done purely for the purpose of performing research then it is called as basic research.

Health Research:

Health research is an application of scientific methods in carrying out investigation or experimentation aimed at discovery of new knowledge or finding solutions of problems. The medical science is concerned with maintaining, improving health, preventing the occurrence of diseases and treating disease conditions. This science is so delicate that even a simple error on the part of health care expert runs havocs. Therefore the medical science demands more efforts of conducting both the basic and the applied research.

Hippocrates summed up the quest for knowledge in medicine and the challenges bound to occur in it as “Life is short while the profession is vast, time is narrow the experimentation is complicated, the destination is exhausting”[4]. Galen explained that “Indeed life became short towards the vastness of the profession while the profession gets vast in the short life because the time spent in every single detailed action becomes exhausting. It is necessary in this profession to study a lot of subjects and indeed, time became short because the element that is spent in this profession is effusing,

spreading into pieces and availably evolving from within itself and from the exterior."

It is widely accepted by experts that health research is more of an empirical research rather than theoretical or conceptual research i.e. it involves observation and experimentation rather than abstraction or framing theory. Hippocrates has been quoted in this regard as "The medical science is hypothesis and experimentation"[5]. At the time of Aflatoon, the doctors were of three categories namely men of hypothesis, men of management and men of experimentation. Abu Bakr Ibn Zakaria Razi (Rhazes) is quoted "Whoever left hypothesis and studying books and sufficed only on experimentation has gone astray"[6].

Even though it is assumed that there is a huge gap of knowledge between the ancient and the modern researchers but the fundamentals of the subject seem to be in great accordance among the experts of the two eras. In fact sometimes the accordance between the two surprisingly surpasses the borderline of fundamentals and goes beyond it. For instance, Rhazes is quoted as "If on a matter all the doctors agree and hypothesis also supports it and experimentation also supports it, then only that matter should be kept in mind and anything opposite to it should be kept aside". This explains and provides the criteria for accepting any novel practice or information and incorporating it in conventional methods.

Research methods and Research Methodology

Research Methods are all the different methods, procedures, tools, etc a researcher employs in performing research. These could include interviews, questionnaires, scales, surveys, polls, observations, etc. The researcher plans them systematically and scientifically as per the requirement of the research project.

Research Methodology is the science which explains the manner in which the research is performed. A researcher plans a methodology for his study by substantiating a systematic way of conducting the study by providing reasons for using a particular method and not using any other method. Thus he describes a way of solving the problem and may predict the outcome as well.

The difference between research methods and research methodology can be explained in a simple way as research methods is just about knowing “what” are the methods of the research whereas research methodology describes “how” the research is conducted. Ibn e Seina described that every profession including medical science is divided into knowledge part and practical part. He is quoted as “One type is about the knowledge of the fundamentals and the other is knowledge of how certain actions are performed”

Objectives of Research

Objectives of Research in Health Sciences

Health research broadly includes clinical, epidemiological, behavioural, and health systems research. Its major objectives are:

1. Identifying Health Problems and Needs

Health research aims to identify the magnitude, distribution, and determinants of diseases. For example, community surveys may reveal high prevalence of anaemia among adolescent girls in a rural area, indicating a need for targeted intervention.

2. Understanding Etiology and Risk Factors

Research investigates causative factors behind diseases, enabling prevention. For instance, identifying tobacco as a risk factor for oral cancer informs public health policies to reduce tobacco consumption.

3. Developing and Testing Interventions

Health research develops new drugs, vaccines, surgical techniques, or behavioural interventions and tests their safety and efficacy. For example, randomized controlled trials are conducted to assess a new antidiabetic medication before approval.

4. Improving Diagnostic Tools and Procedures

A major objective is to develop faster, cheaper, and more accurate diagnostic tools. For instance, rapid antigen tests for COVID-19 were developed to detect infections at point of care.

5. Enhancing Treatment Protocols

Research refines existing treatments to improve outcomes or reduce side effects. E.g., health research may evaluate if a combination therapy is superior to monotherapy in tuberculosis.

6. Evaluating Health Policies and Programmes

Operational research assesses whether public health programmes achieve intended objectives efficiently. For example, assessing National Health Mission initiatives to reduce maternal mortality.

7. Promoting Evidence-Based Practice
Health research aims to provide evidence for clinical guidelines and standard treatment protocols. Without research, medical practice risks relying on tradition rather than evidence.

8. Generating Knowledge for Health Promotion
It seeks to understand behavioural, social, and cultural factors influencing health to design effective health promotion strategies. For example, researching why exclusive breastfeeding rates remain low despite awareness campaigns.

9. Contributing to Global Health Goals
Health research supports objectives such as Universal Health Coverage, Sustainable Development Goals (SDGs), and eradication of specific diseases like polio.

10. Building Capacity and Advancing Science
Finally, research aims to build skills in scientific thinking, critical appraisal, and innovation among health professionals, fostering a culture of lifelong learning and advancement.

Objectives of Research in Unani Medicine

Unani medicine, rooted in Greco-Arabic tradition, views health as a balance of Akhlat (humours) and focuses on holistic healing. Research objectives in Unani are similar in broad framework but adapted to its philosophy and practice.

1. Validation of Classical Concepts
One major objective is to validate classical Unani concepts such as mizaj (temperament), tabiyat (innate faculty), and quwwat mudabbira badan (regulative faculty) with modern biomedical or physiological parameters for academic and professional integration.

2. Standardisation and Quality Control
Research aims to standardise single drugs (mufrad) and compound formulations (murakkab) in terms of identity, purity, strength, and safety, using pharmacognostical, phytochemical, and analytical

methods. For example, standardising Majoon Suranjan for rheumatism ensures therapeutic consistency.

3. Safety and Toxicity Evaluation
An essential objective is to establish safety profiles and permissible dosage ranges for Unani drugs to ensure rational use and minimise adverse effects, especially in formulations containing potentially toxic substances like Aconitum or Strychnos.

4. Pharmacological and Clinical Efficacy Studies
Unani research aims to scientifically validate pharmacological actions described in classical texts (e.g. musakkin - analgesic, mufatteh - deobstruent) through experimental and clinical studies, ensuring evidence-based practice.

5. Conservation and Sustainable Use of Medicinal Plants
Research seeks to document, conserve, and cultivate endangered medicinal plants used in Unani medicine to ensure sustainable availability and biodiversity protection.

6. Integration with Modern Healthcare
Another objective is to integrate Unani medicine within mainstream health care systems by demonstrating its role in lifestyle disorders, geriatrics, immunomodulation, and chronic diseases management with evidence.

7. Innovation and New Formulations
Research in Unani aims to develop novel dosage forms such as capsules, syrups, and ointments from traditional formulations to enhance patient compliance, acceptability, and marketability.

8. Revisiting Treatment Protocols
It seeks to refine classical regimens in the light of current clinical patterns and co-morbidities. For example, evaluating Ilaj bil Ghiza (dietotherapy) in metabolic syndrome based on modern nutrition science.

9. Documentation and Preservation of Traditional Knowledge
Research also documents regional practices, formulations, and experiences of traditional practitioners (Hakeems) to preserve the heritage and explore new research leads.

10. Contribution to Global Complementary and Alternative Medicine (CAM) Evidence Base
Unani research aims to contribute to the global CAM literature, enhancing credibility, acceptance, and integration of Unani medicine in national and international health policies.

Comparative Perspective

Objective	Health research	Unani Research
Identification	Disease burden and health needs	Disease patterns relevant to Unani concepts
Explanation	Etiology and risk factors	Pathophysiology in terms of humours and temperament
Intervention	Drug/vaccine development, health programmes	Formulation validation, regimental therapies
Evaluation	Health programme effectiveness	Efficacy of Unani treatments in clinical settings
Application	Evidence-based guidelines	Integrative protocols with validated Unani therapies
Innovation	New technologies and treatments	New formulations, dosage forms, and therapeutic indications

The ultimate objective of research in any field is to generate valid, reliable, and applicable knowledge to benefit individuals and society. In health research, it ensures scientific advancement, effective disease prevention, and improved clinical care. In Unani medicine, research safeguards traditional wisdom, ensures safety and efficacy, and integrates holistic approaches into modern healthcare.

Thus, research in health sciences and Unani medicine, though differing in philosophy and methodology, converge on the same fundamental goal: improving health, healing, and quality of life through systematic pursuit of truth.

Scope of Research in Health Sciences and Unani Medicine

The scope of research refers to the extent, breadth, and depth of areas covered within a discipline to achieve its objectives. It defines the boundaries within which research operates and expands knowledge. In health sciences and Unani medicine, research scope is vast due to evolving disease patterns, emerging health needs, and integration with global healthcare systems.

Scope of Research in Health Sciences

Health sciences research encompasses diverse disciplines, from clinical medicine to epidemiology, public health, behavioural sciences, and health systems research. Its broad scope includes:

1. Biomedical Research

Basic Research: At molecular, genetic, and cellular levels to understand mechanisms of disease (e.g. studying viral replication in HIV).

Translational Research: Converting lab findings into diagnostic tools, therapies, or preventive strategies (bench-to-bedside research).

Pharmacology and Drug Discovery: Identifying and testing new drug molecules, vaccines, and biologics.

Genomics and Precision Medicine: Tailoring treatment to individual genetic profiles (e.g. targeted cancer therapies).

2. Clinical Research

Clinical Trials: Evaluating safety and efficacy of new drugs, vaccines, surgical techniques, devices, or interventions across Phase I-IV trials.

Clinical Epidemiology: Studying disease patterns in patient populations to improve diagnosis, prognosis, and treatment.

3. Public Health Research

Epidemiological Studies: Assessing disease distribution, determinants, and preventive strategies at community and population levels.

Health Systems Research: Analysing healthcare delivery, accessibility, quality, and policy effectiveness.

Health Economics: Evaluating cost-effectiveness of interventions to guide resource allocation.

Environmental Health Research: Investigating effects of environmental exposures on health (e.g. air pollution and respiratory diseases).

Behavioural and Social Science Research: Exploring how behaviour, social structures, and cultural practices impact health (e.g. vaccine hesitancy).

4. Operational Research
Research within health programmes to improve efficiency, quality, and coverage, such as optimizing supply chains for vaccines or ensuring effective disease treatment adherence.

5. Implementation Science
Understanding how to effectively translate research findings into real-world practice, addressing barriers to uptake of proven interventions.

6. Nursing and Allied Health Research
Exploring effective nursing interventions, rehabilitation protocols, and innovations in physiotherapy, occupational therapy, and medical technology.

7. Global Health Research
Addressing transnational health issues such as pandemics, antimicrobial resistance, and health equity across countries.

Scope of Research in Unani Medicine

Unani medicine, with its holistic approach, offers a vast scope of research integrating classical concepts with modern science for safe, effective, and evidence-based practice.

1. Literary and Conceptual Research

Critical Analysis of Classical Texts: Understanding and interpreting terminologies, disease classifications, and therapeutic approaches described in canonical texts like Al Qanoon fil Tib or Kitab al-Hawi.

Validation of Concepts: Scientific validation of Unani concepts such as mizaj (temperament), akhlat (humours), quwā (faculties), and asbab sittah zarooriya (six essential causes).

2. Pharmacognosy and Standardisation Research

Identification and Authentication: Macroscopic, microscopic, and phytochemical studies to identify medicinal plants accurately.

Standardisation: Developing monographs to standardise crude drugs and formulations ensuring consistency in quality, potency, and efficacy.

3. Pharmacological Research

Experimental Studies: Investigating pharmacological actions described classically (e.g. musakkin – analgesic, munzij – maturative) through in vitro and in vivo models.

Toxicological Studies: Establishing safety profiles, permissible doses, and potential toxicities of Unani drugs, especially those containing heavy metals or potent herbs.

4. Clinical Research

Clinical Trials: Evaluating safety and efficacy of Unani formulations in diseases like arthritis, asthma, diabetes, or skin disorders using standard research designs.

Observational Studies: Documenting outcomes of Unani treatments in routine practice for chronic diseases and lifestyle disorders.

5. Regimental Therapy Research (Ilaj bil Tadbeer)
Efficacy Studies: Researching regimens like hijamah (cupping), dalak (massage), hammam (bath therapy), fasd (venesection) in chronic pain, musculoskeletal, and neurological disorders.

Mechanism Studies: Understanding physiological and biochemical mechanisms underlying these therapies.

6. Dietotherapy Research (Ilaj bil Ghiza)
Nutritional Analysis: Analysing Unani dietetics for macro- and micronutrient contents.

Therapeutic Dietetics: Researching specific diets prescribed for diseases in Unani texts for integration with modern nutrition therapy.

7. Drug Development and Formulation Research
New Dosage Forms: Developing syrups, ointments, capsules, and extracts from classical formulations for patient compliance and market acceptance.

Polyherbal Formulations: Exploring synergistic effects of multiple herbs for targeted therapeutic benefits.

8. Conservation and Cultivation Research
Cultivation Practices: Developing agronomical practices for cultivation of medicinal plants ensuring sustainability and quality yield.

Biodiversity Conservation: Documenting and conserving endangered medicinal plant species used in Unani medicine.

9. Integrative Medicine Research
Interdisciplinary Studies: Evaluating how Unani therapies complement modern treatments in chronic diseases, geriatrics, and rehabilitation.

CAM Integration Research: Studying patient outcomes with integrated Unani and Allopathic management for holistic care.

10. Health Systems and Policy Research
Policy Analysis: Researching integration models of Unani medicine in public health programmes and national health systems.

Utilisation Studies: Analysing utilisation patterns, patient satisfaction, and barriers to Unani healthcare services.

11. Intellectual Property and Commercialisation Research
Patenting and Commercialisation: Research on novel Unani formulations or processes for patents and market application to promote industry growth.

Emerging Areas in Scope

1. Bioinformatics and Systems Biology
Health Sciences: Use of bioinformatics in genomics, proteomics, and big data analysis for personalised medicine.

Unani Medicine: Systems biology approaches to understand humoral interactions with molecular pathways.

2. Artificial Intelligence and Digital Health
Health Sciences: AI in diagnostics, treatment planning, and telemedicine.

Unani Medicine: Digitalisation of classical texts, AI-based prescription support systems, and tele-consultation models.

3. Environmental and Climate Change Research
Studying impacts of climate change on disease patterns and medicinal plant availability in both systems.

Comparative Scope Table

Area	Health Sciences	Unani Medicine
Basic Research	Molecular & genetic studies	Conceptual & classical text analysis
Clinical Research	Trials of new drugs/devices	Trials of formulations & regimens

Public Health	Epidemiology, policy, systems	Integration in public health programmes
Pharmacology	Synthetic & natural drugs	Herbal pharmacology & validation
Diagnostics	Biomarkers, imaging	Mizaj assessment tools, pulse diagnosis validation
Therapeutics	Drug therapy, surgery, rehabilitation	Ilaj bil Tadbeer, Ghiza, Dawa
Innovation	AI, robotics, biotechnology	Novel formulations, digitalisation of knowledge

The scope of research in health sciences is vast, embracing fundamental, applied, and translational research to improve health outcomes and advance medical knowledge. In Unani medicine, it ranges from validation and standardisation of age-old wisdom to modern clinical and pharmacological studies for global integration.

Both disciplines, despite differing epistemologies, share a common vision: improving human health, preventing diseases, and enhancing quality of life through systematic, ethical, and impactful research.

Historical Development of Contemporary Research

Contemporary research, as practiced today across sciences and humanities, is the product of centuries of philosophical, scientific, and methodological evolution. From early human curiosity to structured scientific enquiry, research developed through contributions from various civilizations and epochs, culminating in the systematic, ethical, evidence-based approach that defines modern research.

Early Roots of Research

1. Ancient Civilizations

Mesopotamia and Egypt: Early forms of observational research in agriculture, astronomy, and medicine. Egyptians documented surgical techniques and herbal remedies in Ebers Papyrus.

Indian Subcontinent: Systematic classification of knowledge in Vedas, Ayurveda's detailed observation-based therapeutic formulations, and Charaka-Sushruta Samhitas emphasising empirical observations.

China: Research traditions focusing on observation, documentation, and systematisation in medicine (e.g. Huangdi Neijing).

2. Greek Contributions

Philosophical Enquiry: Greeks shifted from mythological explanations to rational enquiry. Socrates emphasised logical questioning; Plato developed deductive reasoning; Aristotle advanced inductive reasoning, systematic observation, and classification – foundations of empirical science.

Medicine: Hippocrates introduced clinical observation and ethical guidelines, laying groundwork for research in medicine.

Islamic Golden Age (8th–14th century)

A major leap in systematic research occurred in the Islamic world:

Translation Movement: Knowledge from Greek, Persian, and Indian sources was translated into Arabic in Baghdad's Bayt al-Hikma (House of Wisdom).

Original Research: Scholars like Al-Razi (Rhazes) conducted comparative studies of diseases; Ibn Sina (Avicenna) wrote Al-Qanun fil Tib, combining clinical observation with philosophical reasoning.

Methodological Developments: Alhazen (Ibn al-Haytham) pioneered experimental scientific methods in optics, emphasising hypothesis testing and reproducibility, core to modern research methodology.

European Renaissance and Enlightenment

1. Renaissance (14th–17th century)
Revival of Greek and Islamic texts sparked interest in observation and human anatomy (e.g. Vesalius' De Humani Corporis Fabrica revolutionised anatomical research).

Inventions like the printing press (Gutenberg) accelerated knowledge dissemination, fuelling research across disciplines.

2. Scientific Revolution (16th–18th century)
Empiricism: Francis Bacon formalised inductive reasoning in Novum Organum, advocating systematic observation and experimentation.

Mathematical Formulation: Galileo integrated experimentation with mathematical analysis, advancing physics research.

Newton: His Principia Mathematica exemplified research integrating observation, hypothesis, experimentation, and mathematical proof.

3. Enlightenment Era
Emphasis on rationality and systematic enquiry extended research into social sciences, economics (Adam Smith), and political philosophy (Rousseau, Locke).

19th Century – Institutionalisation of Research

1. Rise of Universities and Research Institutions

- Universities began prioritising research alongside teaching (e.g. University of Berlin).

- Laboratories became central to research, especially in chemistry (Lavoisier), physiology (Claude Bernard's experimental medicine), and microbiology (Pasteur, Koch).

2. Development of Research Methodology

- Emergence of statistics (Gauss, Laplace) introduced quantitative analysis in research.
- Evolutionary theory by Darwin showcased systematic observation, data collection, and theory formulation.
- Social sciences formalised methods: Comte's positivism advocated scientific approach to social enquiry; Durkheim employed statistical analysis in sociology.

20th Century – Modernisation and Diversification

1. Technological and Scientific Advancements

- Quantum physics, relativity, molecular biology, and genetic research (e.g. Watson & Crick's DNA structure discovery) redefined scientific paradigms.
- Research shifted from individual-based to team-based, interdisciplinary models.

2. World Wars and Research Funding

Wars accelerated research in medicine, engineering, and nuclear sciences. Post-war, governments institutionalised research funding (e.g. NIH in USA, CSIR in India).

3. Development of Ethical Frameworks

Atrocities during WWII led to formulation of research ethics codes: Nuremberg Code (1947), Declaration of Helsinki (1964), Belmont Report (1979) emphasising informed consent, beneficence, and justice.

4. Rise of Evidence-Based Practice: In medicine, Archie Cochrane's advocacy in the 1970s led to Evidence-Based Medicine (EBM), integrating clinical expertise with systematic research evidence.

5. Social Science Methodological Expansion

Development of qualitative methodologies (phenomenology, ethnography, grounded theory) alongside quantitative methods broadened the scope of research approaches.

Contemporary Research Landscape (21st Century)

1. Digital Revolution and Big Data

Digitalisation, AI, and big data analytics transformed research capabilities in genomics, epidemiology (e.g. COVID-19 data modelling), and social sciences (social media analytics).

2. Globalisation and Multicentric Research

Collaboration across countries in clinical trials, climate research, and health systems strengthened evidence generalisability and impact.

3. Translational and Implementation Research

Bridging gap between lab discoveries and practical application became a priority (bench-to-bedside approach), especially in health research.

4. Integrative and Interdisciplinary Research

- Integration across disciplines (e.g. bioinformatics, systems biology) for complex problem-solving.
- CAM research, including Unani and Ayurveda, is undergoing scientific validation to integrate into global health systems.

5. Focus on Research Impact and Sustainability

Funding bodies now prioritise research with social, economic, and policy impact alongside academic excellence.

6. Research Ethics, Integrity, and Open Science

- Emphasis on transparency, data sharing, plagiarism prevention, and equitable authorship strengthened research integrity.
- Open Access publishing models democratise knowledge availability.

Contemporary research stands on centuries of evolution from curiosity-driven observations to systematic, evidence-based, and ethical enquiry. Its historical development reflects:

- The journey from myth to reason,
- From individual philosophical reflections to institutionalised science, and
- From disciplinary silos to interdisciplinary, global collaboration.

- Today, research is not just the pursuit of knowledge but a structured approach to solve real-world problems, improve lives, inform policies, and advance collective human understanding.

Evidence of Research in Classical Unani Literature

Unani medicine, also known as Tibb-e-Unani, is a system of medicine rooted in Graeco-Arabic medical knowledge. It traces its foundations to ancient Greece and was further expanded and refined by Roman, Persian, Arab, and Indian scholars over several centuries. The tradition is deeply intertwined with the philosophical underpinnings of empiricism, rationalism, and systematic inquiry. Far from being merely a practice of healing, classical Unani medicine has a rich tradition of scientific research, clinical experimentation, materia medica exploration, and diagnostic innovation — all captured in its classical literature.

The evidence of research can be examined throughout the classical Unani tradition by analyzing its core texts and intellectual currents, and by highlighting the work of prominent physicians from Greece, the Arab world, Persia, and India.

1. The Greek Foundations: Rational Inquiry and Humoral Theory

The initiators of the systemized medical model in the West were Greek physicians such as Hippocrates and Galen, whose methodologies were later absorbed into the Unani tradition.

Hippocrates (Buqrat)

Often referred to as the "Father of Medicine," Hippocrates introduced the humoral theory, positing that health and disease are governed by the balance of four bodily humors: blood, phlegm, yellow bile, and black bile. His clinical methods emphasized:

- Observation over speculation, by encouraging physicians to gather patient histories, observe symptoms, and track disease progression;
- Natural explanations for disease, replacing the theological or supernatural interpretations prevalent in earlier cultures;
- Prognostic analysis, using knowledge of symptoms to predict disease outcomes—a method that required extensive empirical data collection.

His emphasis on methodical documentation and prognosis foreshadowed modern case reporting and epidemiological tracking.

Galen (Jalinoos)

Building on Hippocratic foundations, Galen broadened clinical research by integrating anatomy, physiology, and logic. His contributions included:

- Experimental anatomy, derived from animal dissection, which significantly improved understanding of organ function;
- Differential diagnosis, systematizing the classification of diseases;
- Pharmacological trial and error, developing standardized compound drugs and observing their effects over time.

Galen's works, particularly his treatises on therapeutics, surgery, and medicinal theory, were rigorously structured—each diagnosis was informed by empirical observations, logical conclusions, and repeatable outcomes. This triad of observation–reasoning–testing became core to later Unani methods.

2. Islamic and Persian Refinements: Systematic Compilation and Clinical Protocols

With the advent of Islamic civilization, the Unani corpus expanded dramatically, particularly under the Abbasid Caliphate. Scholars translated Greek texts into Arabic and added commentaries infused with clinical insights linked to Islamic epistemologies.

Rhazes (Al-Razi)

A polymath rooted in empirical sciences, Rhazes demonstrated a profound commitment to observational clinical medicine. His magnum opus, Kitab al-Hawi (The Comprehensive Book), is an encyclopedic medical work that:

- Liberally cited Hippocratic and Galenic opinions before critiquing or confirming them through his own clinical observations;
- Presented case studies and therapeutic outcomes as records of real-life encounters;
- Highlighted the importance of multiple trials before validating a treatment.

He also appears to have attempted early forms of clinical differentiation between diseases such as measles and smallpox—something that required continuous data collection and patient studies.

Avicenna (Ibn Sina)

Avicenna's Al-Qanun fi al-Tibb (The Canon of Medicine) is a towering achievement in the synthesis of Greek rationalism and Islamic naturalism. His contributions to medical methodology are monumental:

- Introduced a systematic protocol for drug testing, establishing guidelines that mirror principles found in controlled modern trials;
- Emphasized repeatability, dosage escalation, and side-effect profiling of substances;
- Proposed structured medical education based on logical sequencing (from causes to symptoms to treatment), integrating philosophy with medical practice;
- Elevated clinical reasoning, encouraging differential diagnosis and diagnosis by exclusion.

The presence of logical syllogism and deductive reasoning within his clinical recommendations signifies a formalized medical methodology that deeply influenced centuries of practice in Central Asia, the Middle East, and South Asia.

Al-Zahrawi (Abu al-Qasim)

Renowned particularly for his contributions to surgery, Al-Zahrawi's Al-Tasrif is not only a surgical manual but a repository of operative innovation. In it, he:

- Documented over 200 surgical instruments, many of his own invention;
- Argued for the importance of firsthand experimentation over text-based knowledge;
- Advocated for pre-surgical and post-surgical documentation, including patient condition, procedural parameters, and pharmacological interventions.

This level of clinical documentation speaks of a culture of procedural audits and case-based translation of theory into practice.

3. The Indo-Islamic Expansion: Integration and Localization of Research: The Mughal arrival in India brought with it a vast expansion of Unani medicine, as Persian and Arabic texts were taught in Indian madrasas, and clinical practice became part of the royal medical services.

Azam Khan and Synthesis of Traditions

One of the foremost intellectuals of Indian Unani medicine, Hakim Azam Khan authored several major treatises including Makhzan al-Adwiya and Tibb-e-Azam. His work particularly emphasized:

- Empirical testing of indigenous Indian herbs through Unani frameworks;
- Integration of Siddha and Ayurveda pharmaceutics within Unani matrices, creating a hybrid therapeutic landscape;
- Repeated clinical validation, often recorded in detail in Urdu for wider dissemination among local practitioners.

Azam Khan was a bridge between theoretical medicine inherited from Arabic classics and practical medicine adapted to Indian diseases, climates, and herbs.

Hakeem Families and Medical Practice as Research

Cities like Delhi, Aligarh, Lucknow, Hyderabad, and Bhopal became centers of Unani research and practice. Distinguished families in these regions—such as the Sharifi and Ajmal families—maintained medical lineages across centuries.

These families:

- Preserved handwritten bayaz (clinical notebooks) written in Urdu and Persian which often contained real-time observational notes;
- Ran madrasas-tibbia, medical schools where students performed drugs trials, learned about diagnosis, and engaged in systematic inquiry;
- Maintained correspondence with Western-trained physicians and incorporated germ theory, pharmacokinetics, and allopathic parallels into study.

Their recorded experiences reflect not rote traditionalism, but an active pursuit of practical knowledge based on repeatable outcomes.

4. Methodologies of Research Evident in Unani Tradition

Unani medicine embraced a multi-faceted approach to research that resonated with principles of modern scientific inquiry. At its root, it combined both deductive reasoning (qiyas) and empirical testing (tajriba), resulting in a layered framework for medical investigation.

Key Research Methods:

- Mushahada (Observation): The groundwork of patient evaluation was laid through detailed continuous observation—symptoms, pulse, urine color, temperament (mizaj), and recovery patterns.
- Tajruba (Experiment): Physicians designed and tested therapies by observing outcomes across multiple applications. It was acceptable only when experiments were reproducible and side effects predictable.
- Tafakkur (Reasoning): Utilizing philosophical logic, theorization about unseen processes (e.g., causes of fever or digestion) involved analogical and deductive reasoning.
- Istiqra (Induction): Through accumulation of multiple case outcomes, general principles of treatment were derived — moving from specific observations to universal medical laws.

5. Institutions of Research and Transmission

From the 10th century onwards, medical schools across Baghdad, Nishapur, Cordoba, and later Delhi and Lucknow served as both therapeutic and learning centers. These institutions:

- Supported collective authorship and critique, especially with commentaries on canonical texts;
- Maintained manuscript traditions that recorded not only therapies but also patient experiences and innovations;
- Encouraged case-based training, sometimes supervised by master hakims (ustad)—imitating teacher-pupil clinical mentorship models akin to Western medical residencies.

6. Innovation through Integration

A profound strength of Unani medicine was its ability to adopt and adapt. In India, this meant:

- Introduction of new herbs and minerals from Ayurvedic and Siddha sources into Unani formulations;

- Acceptance of European insights in pathology and bacteriology (e.g., post-Germ Theory integration in the 19th–20th centuries);
- Dialogue between Unani hakims and allopathic doctors, especially under colonial medical pluralism.

Such cross-systemic synthesis was possible only through a rigorous research culture that allowed Unani to selectively expand and revise its pharmacological and clinical corpus.

7. A Legacy of Rigorous Inquiry

Far from being a static body of inherited tradition, classical Unani literature embodies a vibrant tradition of systematic research across generations and geographies. From the incisive observations of Hippocrates to the sophisticated pharmacological protocols of Ibn Sina, from the surgical innovations of Al-Zahrawi to the clinical pragmatism of Azam Khan and Indian Hakims, the Unani system stands as a testament to the intellectual rigor underpinning Islamic and Indo-Hellenistic medical traditions.

Its literature offers layers of evidence supporting research in all its modern senses — trial, observation, inference, and reproducibility. Today, these manuscripts and casebooks continue to inform contemporary Unani practice while serving as valuable historical documentation of the evolution of empirical medicine.

Chapter 2.
Evidence-Based Medicine (EBM) and Integrative Medicine

I. Introduction

Modern healthcare increasingly emphasises Evidence-Based Medicine (EBM) and Integrative Medicine (IM) to ensure effective, safe, and patient-centred care. These concepts are essential to understand contemporary clinical practice, Unani medicine integration, and research approaches.

II. Evidence-Based Medicine (EBM)

1. Definition

EBM is "the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients." (Sackett et al., 1996)

It integrates:

- Best Research Evidence: From systematic research.
- Clinical Expertise: Experience and judgement of practitioners.
- Patient Values and Preferences: Unique needs, concerns, expectations.

2. Importance of EBM

- Ensures clinical decisions are scientifically justified rather than based on tradition or opinion alone.
- Improves patient safety and outcomes.
- Supports cost-effective healthcare by eliminating ineffective interventions.
- Enhances clinical skills, critical appraisal, and lifelong learning in practitioners.
- Provides standardised treatment guidelines based on strong evidence.
- Promotes ethical practice by reducing harm and maximising benefit.

III. Levels of Evidence in EBM

The hierarchy of evidence reflects the strength and reliability of evidence. Commonly used levels (adapted from Oxford Centre for EBM) are:

Level	Type of Evidence
Level 1a	Systematic reviews of randomised controlled trials (RCTs)
Level 1b	Individual RCT with narrow confidence interval
Level 2a	Systematic review of cohort studies
Level 2b	Individual cohort study or low-quality RCT
Level 3a	Systematic review of case-control studies
Level 3b	Individual case-control study
Level 4	Case series, poor-quality cohort/case-control studies
Level 5	Expert opinion without explicit critical appraisal

Higher levels indicate greater validity and reliability, critical for framing guidelines and recommendations.

IV. Research Process in Evidence-Based Medicine

The EBM research process is systematic:

1. Asking Focused Questions (PICO)

P: Patient/problem
I: Intervention
C: Comparison
O: Outcome

Example: In patients with osteoarthritis, does Unani Majoon Suranjan compared to NSAIDs reduce pain effectively?

2. Searching for Evidence

Use of databases: PubMed, Cochrane, Scopus, AYUSH Research Portal.

3. Critical Appraisal

Evaluating:

Validity (bias, confounders)
Results (effect size, significance)
Applicability to patient care

4. Applying Evidence

Integrating best evidence with clinical expertise and patient preferences.

5. Evaluating Outcomes

Monitoring patient response to ensure effective implementation.

V. Integrative Medicine (IM)

1. Definition

Integrative Medicine is an approach combining conventional (Allopathic) medicine with Complementary and Alternative Medicine (CAM) modalities (e.g. Unani, Ayurveda, Yoga) in a coordinated way, emphasising:

- Holistic care (body, mind, spirit, social context)
- Evidence-based use of both systems
- Patient-centred focus

2. Principles of Integrative Medicine

- Holism: Treating the whole person.
- Individualisation: Personalised treatment plans.
- Prevention and Wellness: Not merely disease management.
- Evidence-based integration: Using therapies with proven safety and efficacy.

3. Importance of Integrative Medicine

- Addresses chronic, lifestyle, and psychosomatic disorders effectively.
- Enhances patient satisfaction and trust.
- Reduces side effects of conventional treatments (e.g. using Unani hepatoprotective herbs with Allopathic hepatotoxic drugs).
- Promotes interdisciplinary collaboration among health professionals.
- Contributes to universal health coverage through affordable traditional therapies.

VI. Current Status of Unani Medicine Research

1. Institutional Framework

- Central Council for Research in Unani Medicine (CCRUM) under Ministry of AYUSH, India, spearheads Unani research with peripheral institutes nationwide.
- National Research Institutes in Hyderabad, Lucknow, Delhi, Chennai conduct clinical, pharmacological, and literary research.
- Unani Colleges with PG/PhD programmes integrate research into education (e.g. Jamia Hamdard, AMU Aligarh).

2. Key Research Areas

a. Clinical Research

- Evaluating efficacy and safety of classical formulations (e.g. Majoon Suranjan in arthritis, Jawarish Jalinus in digestive disorders).
- Standardised RCTs, observational studies, and pilot trials are conducted under CCRUM protocols.

b. Pharmacological Research

- Validating classical actions (af'al) through in vitro and in vivo studies (e.g. anti-inflammatory, analgesic, hepatoprotective actions).
- Toxicity studies to establish safety profiles.

c. Literary Research

- Critical editions and translations of manuscripts.
- Digital archiving of rare Unani texts for preservation and academic access.

d. Drug Standardisation Research

- Developing pharmacopoeial standards, monographs, analytical profiles, and fingerprinting using modern techniques (HPTLC, GC-MS).

e. Regimental Therapy Research

- Clinical trials on hijamah (cupping), dalak (massage), hammam (bath therapy), fasd (venesection) for musculoskeletal, neurological, and lifestyle disorders.

f. Dietotherapy Research

- Nutritional profiling of Unani diets and validation of Ilaj bil Ghiza recommendations for chronic diseases.

3. Challenges in Unani Research

- Limited high-quality RCTs with large sample sizes.
- Insufficient international publication visibility.
- Lack of advanced laboratory infrastructure in many institutes.
- Need for capacity building in research methodology among practitioners.

VII. Current Status of Integrative Medicine Research

1. Global Perspective

- National Institutes of Health (NIH), USA: Established National Center for Complementary and Integrative Health (NCCIH).
- WHO: Promotes traditional and integrative medicine within health systems for Universal Health Coverage.
- China and Korea: Integrated traditional medicine with mainstream healthcare effectively.

2. India's Integrative Medicine Initiatives

- Ministry of AYUSH: Policy for integrative research and education.
- AIIMS Delhi and CCRAS/CCRUM: Joint research on integrating Ayurveda/Unani with Allopathic management in conditions like COVID-19, diabetes, and arthritis.
- NITI Aayog Committee: Developing integrative health guidelines and institutional frameworks.

3. Current Integrative Research Projects in Unani

- Unani formulations as adjuvant therapy in diabetes, osteoarthritis, and respiratory illnesses alongside Allopathic treatment.
- Hijamah research for pain management integrated with physiotherapy.
- Ilaj bil Ghiza studies complementing Allopathic dietary management in metabolic syndrome.

VIII. Future Directions in Unani and Integrative Medicine Research

1. Emphasis on High-Quality Evidence

- Designing double-blind, randomised controlled trials with robust methodology.
- Publishing in indexed international journals for global recognition.

2. Multi-centric Collaborative Research

- Collaboration with Allopathic institutes for integrative clinical trials.
- Partnerships with pharmacology, botany, and biotechnology departments for drug discovery and validation.

3. Application of Modern Techniques

- Pharmacogenomics: Understanding how Unani drugs act on genetic profiles.
- Systems biology approaches: To explore holistic action mechanisms.
- AI and Data Science: For Unani text mining, formulation development, and integrative health modelling.

4. Strengthening Ethical and Regulatory Frameworks

- Ensuring adherence to Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and AYUSH Research Guidelines.
- Establishing Integrative Medicine Ethics Committees for multidisciplinary research approval.

Evidence-Based Medicine (EBM) ensures clinical practices are grounded in reliable scientific evidence, integrated with practitioner expertise and patient preferences. Its structured process and hierarchy of evidence empower rational, safe, and effective healthcare delivery.

Integrative Medicine (IM) combines conventional medicine with CAM systems like Unani to provide holistic, patient-centred care addressing not only disease but overall wellness.

The current status of Unani research reflects progress in clinical validation, pharmacology, regimental therapies, and standardisation,

while integrative medicine research is advancing with institutional initiatives, collaborative studies, and policy frameworks.
Moving forward, strengthening methodological rigour, interdisciplinary collaboration, international publication, and ethical standards will ensure Unani medicine contributes meaningfully to evidence-based integrative healthcare for the benefit of humanity.

Research Works of CCRUM in Unani Medicine Since Its Inception

The Central Council for Research in Unani Medicine (CCRUM), established in 1978, is the apex autonomous research organization under the Ministry of Ayush, Government of India. For over four decades, CCRUM has played a pioneering role in advancing Unani medicine through broad-ranging scientific investigation, validation studies, and knowledge dissemination. Through a nationwide network of 23+ research centers, CCRUM's mission is to bring evidence-based practice and credibility to Unani medicine, preserve its heritage, and integrate it into contemporary healthcare systems.

1. Organizational Mandate and Research Framework

Mandate: To conduct scientific research in fundamental and applied aspects of Unani medicine, develop pharmacopoeial standards, validate therapies, conserve medicinal plant resources, revive classical literature, and promote public health.
Objective Areas:

- Fundamental and applied research
- Drug standardization
- Literary research (translation and preservation)
- Survey and cultivation of medicinal plants
- Collaborative and extramural research
- Dissemination and public health integration

2. Major Domains of Research

2.1 Clinical Research: Clinical research is the core activity of CCRUM. Targeted studies aim to validate both classical and new Unani

formulations for efficacy, safety, and cost-effectiveness across a wide range of ailments.
- Multicentre Clinical Trials: Conducted on both single drugs and compound formulations for conditions such as:
 - Chronic Diseases: Diabetes, hypertension, asthma, rheumatoid arthritis, psoriasis, vitiligo, hepatitis, and more
 - Epidemics and Infectious Diseases: Gastroenteritis, cholera, dengue, viral fevers, chikungunya, jaundice
- Regimen Therapies: SOPs and protocols have been established for leech therapy, cupping, Turkish bath, massage, and other practices, with evidence-based validation.
- OPD and Healthcare Integration: Unani drugs and therapies are routinely used in Outpatient Departments (OPDs), often integrated into government-run public health initiatives and national disease prevention programs.

Key Achievements
- Over 130 randomized clinical trials completed, with 50+ ongoing
- Validated efficacy for more than 30 diseases with around 120 drugs/formulations screened
- Developed novel Unani-based kits for common/seasonal ailments (e.g., cough drops, ORS, galactagogue biscuits, herbal teas) now being commercially exploited
- Effective Unani protocols established for women's health, aging, and cosmetic conditions

2.2 Drug Standardization and Quality Assurance
- Pharmacopoeial Standards: Pharmacopoeial standards have been developed for over 338 single and 200 compound Unani drugs, ensuring consistent quality and safety.
- Analytical Advances: Modern analytical techniques (HPTLC, GC-MS, DNA barcoding) are employed for authenticity, purity, and potency assessments.
- National Formulary: Six volumes of the National Formulary of Unani Medicine have been produced and updated.
- Patents: Seventeen patents have been awarded for innovative formulations/processes.

Highlights

Activity	Achievements
Pharmacopoeia standards	338 single + 200 compound drugs
Drug safety/toxicology	Safety studies for 115 single drugs; pharmacological studies for 70 formulations
Patents	17 patents
National Formulary revision	6 volumes, updated regularly

2.3 Survey and Cultivation of Medicinal Plants

- Documentation: Surveyed and catalogued over 100,000 medicinal plant specimens from 5,000 species, documenting 10,000+ folk medicinal claims and practices[3][5].
- Conservation: Cultivation and maintenance of 30 selected medicinal plants and a living collection of over 400 rare/endangered species.
- Ethnobotanical Studies: Collaboration with tribal and rural populations for ethnomedicinal documentation.

2.4 Literary Research and Heritage Revival

- Translation & Compilation: Translated 66 volumes of classical Unani books, compiled 22 books, and reprinted over 70 rare classical manuscripts.
- Development of Terminologies: Standardized Unani terminologies and prepared reference texts.
- Guidelines: Issued treatment protocols and clinical guidelines for common diseases.

2.5 Research on Fundamentals

- Conducted more than 30 studies on core principles of Unani medicine—including temperament theory (mizaj), humoral balance, and regimental therapies—aligning traditional understanding with contemporary biological sciences.

2.6 Public Health and Community Outreach

- Integration with National Health Programs: Participation in programs for prevention and control of major diseases (cancer, diabetes, cardiovascular diseases, stroke) under the National Programme for Prevention and Control of Cancer, Diabetes, CVD, and Stroke (NPCDCS).
- Mobile Clinics and Health Camps: Operated mobile clinics and health extension units, bringing Unani healthcare to underserved populations.

- School Health Program: Implemented health screening and hygiene education in public schools.

2.7 Education, Capacity Building, and International Collaboration

- Postgraduate Training: Established MD/PhD programs in Unani medicine at premier institutions; promotes the Studentship Program for Unani Research (SPUR) to encourage undergraduate research participation.
- Skill Development: Organized regular workshops, CME programs, and certification courses.
- Global Collaborations: MoUs with international institutions (e.g., Iran, Bangladesh, Tajikistan, South Africa) for joint research, academic exchange, and scientific dialogue.

3. Significant Milestones and Case Studies

3.1 Efficacy in Disease Management

- Diabetes & Metabolic Disorders: Multicentric trials of polyherbal Unani formulations demonstrated significant reduction in fasting glucose and improved glycemic control.
- Respiratory Disorders: Development of clinical protocols for asthma, bronchitis, and COPD relief through Unani therapies validated by randomized controlled trials.
- Rheumatology & Dermatology: Safe, cost-effective Unani treatments for musculoskeletal diseases (e.g., rheumatoid arthritis) and skin disorders (e.g., eczema, vitiligo, psoriasis).
- Infectious Outbreaks: Scientific management and validation for Unani remedies during epidemics like dengue, chikungunya, gastroenteritis, jaundice, and cholera.
- Women's & Geriatric Health: Specialized protocols for menstrual disorders, infertility, and healthy aging, including validated drug packages for senior citizens.

3.2 Innovation in Products and Therapies

- Commercial Products: Successful development and commercialization of Unani-based products for cough, diarrhea, lactation, as well as herbal teas.

- Regimen Therapies: Development and scientific validation of SOPs for unique Unani regimental therapies (leeching, cupping, massage, etc.).

3.3 Drug Authentication and Quality Assurance

- DNA Barcoding & Chromatography: Use of molecular diagnostics to ensure identity and safety of raw materials.
- Quality Control Modernization: Adherence to international standards (NABL/NABH) in laboratory and clinical research infrastructure.

4. Data, Publications, and Recognition

- Publications: Hundreds of research papers published in reputed journals; over 1,400 presented at seminars, conferences, and workshops globally.
- Patents: 17 innovative patents for formulations and procedures.
- Treatment Outreach: CCRUM's OPDs treat more than 500,000 patients annually.

5. Integration with National Healthcare

- AYUSH Co-location: Unani centers established in leading allopathic hospitals for collaborative patient care (e.g., RML, DDU, Safdarjung Hospital, AIIA in Delhi).
- Pandemic Response: During COVID-19, developed and recommended Unani prophylactic measures, published related research, and raised public awareness

6. Programme Expansion and Future Outlook

6.1 New Centers and Digitization

- Research Centre Network: 23+ centers and laboratories nationwide to address local health needs.
- Digitization: Adoption of electronic health records, digital data management platforms for better research and patient care outcomes.

6.2 Ongoing and Future Research

- Rare Diseases and Emerging Health Challenges: Proposals and studies on rare diseases, long-COVID, and chronic lifestyle disorders.
- Translational Research and Industry Collaboration: Emphasis on industry ties, clinical translation of laboratory findings, and participation in global health initiatives.

7. Important Highlights

Area of Contribution	Achievement/Output
Research Studies Completed	>130 randomized clinical trials; 30+ fundamentals studies; 115 toxicology studies
Drug Standardization	338 single drugs, 200 compound drugs, 6 National Formulary volumes
Patents Granted	17
Literary Works (Translations/Books)	66 classical book translations, 22 compilations, 70+ reprints
Plants Surveyed/Documented	100,000+ specimens, 5,000+ species, 10,000+ folk claims
Clinical Protocols Developed	For >30 diseases (Chronic diseases, epidemics, lifestyle illnesses)
Beneficiaries in OPD annually	500,000+ patients
Scientific Publications/ Presentations	Hundreds of papers in national/international journals; 1,400+ conference presentations
International/Collaborative Agreements	MoUs with institutions across Asia and Africa

8. Challenges and Lessons Learned

- Data Consistency: Variation in patient data and outcomes across multiple centers.
- Regulatory Hurdles: Lengthy processes and budgetary limitations for advanced molecular/genetic research.
- Scalability: Bringing validated pilot therapies to wider populations requires collaboration with industry and regulatory agencies.
- Heritage and Innovation Balance: Need to maintain classical roots while incorporating contemporary scientific advances.

9. Impact and Global Influence

- Recognition: CCRUM's work has brought significant visibility and credibility to Unani medicine within AYUSH and traditional medicine systems worldwide.
- Global Dialogues: Participation in international conferences, building Unani's reputation beyond Indian borders.
- Integration: Growing acceptance and utilization of Unani medicine in mainstream healthcare and public health programs.

Conclusion

Since its inception, CCRUM has been a beacon for the advancement of Unani medicine—merging ancient wisdom with modern scientific rigor. From clinical trials and drug standardization to medicinal plant documentation, literary preservation, global collaborations, and public health integration, the Council stands at the forefront of research innovation in Unani medicine.

Its evidence-based approach and dedication to public wellbeing lay a robust foundation for Unani medicine's continued relevance and expansion as a system of holistic, preventive, and personalized healthcare.

Chapter 3.
Types of Research

Basic, Applied, and Translational Research

Research can be categorised based on its purpose and application into:

1. Basic (Fundamental) Research
2. Applied Research
3. Translational Research

Understanding these is essential for framing objectives, designing studies, and interpreting outcomes in health sciences, Unani, and integrative medicine research.

I. Basic Research

1. Definition

Also known as fundamental or pure research, basic research is conducted to generate new knowledge, concepts, or theories, without immediate practical application in mind.

2. Characteristics

- Driven by curiosity and the quest for understanding.
- Explores underlying mechanisms, principles, or phenomena.
- May not yield immediate solutions but forms the foundation for future applied research.

3. Examples

Field	Example of Basic Research
Health Sciences	Studying how a virus enters human cells at the molecular level.
Unani Medicine	Investigating the physiological basis of mizaj (temperament) or humoural theory using biochemical and genetic analysis.
Pharmacology	Understanding mechanisms of action of herbal constituents without targeting specific diseases immediately.

4. Importance

- Expands scientific knowledge base.

- Generates hypotheses for applied research.
- Leads to discovery of new pathways, targets, or principles crucial for innovation.

III. Applied Research

1. Definition

Applied research is conducted to solve specific, practical problems by applying existing theories or knowledge generated from basic research.

2. Characteristics

- Goal-oriented, addressing real-world needs.
- Results have direct practical application.
- Bridges knowledge with societal benefit.

3. Examples

Field	Example of Applied Research
Health Sciences	Developing a vaccine using knowledge of viral protein structures.
Unani Medicine	Testing efficacy of Majoon Suranjan in osteoarthritis through clinical trials.
Public Health	Studying effectiveness of a health education program to improve sanitation practices.

4. Importance

- Solves immediate health, industrial, and societal issues.
- Contributes to economic development and quality of life.
- Translates basic discoveries into practical solutions.

IV. Translational Research

1. Definition

Translational research aims to "translate" basic research findings into clinical or public health applications to improve patient outcomes, bridging the "bench-to-bedside" gap.

2. Characteristics

- Multi-disciplinary approach involving basic scientists, clinicians, public health experts, and policymakers.
- Moves knowledge through stages:

  T1: From laboratory (basic science) to human trials.

T2: From clinical trials to practice guidelines.
T3: From guidelines to health practice and policy.
T4: Evaluating real-world health impact.

3. Examples

Field	Example of Translational Research
Health Sciences	Developing monoclonal antibody therapies for cancer after identifying molecular targets.
Unani Medicine	Validating hepatoprotective herbs in animal models (basic research), testing formulations in human trials (applied research), and integrating results into national hepatitis management programmes (translational research).
Public Health	Implementing and assessing national TB control strategies based on research findings.

4. Importance

- Accelerates the application of scientific discoveries to patient care.
- Improves health systems and policies.
- Maximises the impact of research investments on population health.

V. Comparative Summary

Aspect	Basic Research	Applied Research	Translational Research
Purpose	Knowledge generation	Solving practical problems	Applying discoveries to clinical/public health practice
Focus	Theoretical concepts and mechanisms	Development and evaluation of solutions	Implementation into practice and policy
Outcome	New theories, models, or understanding	Products, interventions, techniques	Improved healthcare delivery and outcomes
Example	Studying	Developing an	Integrating

	immune cell signalling pathways	immunotherapy drug	immunotherapy into cancer treatment protocols

All three types of research are interdependent and complementary:

- Basic research lays the foundation.
- Applied research uses this knowledge to create practical solutions.
- Translational research ensures these solutions reach patients, communities, and policies effectively.

Understanding their distinct roles enhances research planning, funding justification, and interdisciplinary collaboration, crucial for progress in Unani medicine, integrative medicine, and health sciences.

Qualitative, Quantitative, and Mixed Methods Research

Based on the nature of the data collected and analysed, research methodologies are broadly categorised into:

1. Qualitative Research
2. Quantitative Research
3. Mixed Methods Research

Understanding each is essential to design effective studies in health sciences, Unani medicine, and integrative medicine.

Qualitative Research

1. Definition

Qualitative research is an approach to explore meanings, experiences, interpretations, and phenomena in depth. It focuses on "why" and "how" questions rather than "how many" or "how much."

2. Characteristics

- Nature: Exploratory, descriptive, subjective.
- Data: Non-numerical – words, observations, texts, images.
- Sampling: Small, purposive samples selected for information richness.
- Methods:
  - In-depth interviews (structured, semi-structured, unstructured)
  - Focus group discussions
  - Participant observation
  - Document and content analysis
- Analysis: Thematic analysis, grounded theory, phenomenology, narrative analysis.
- Outcome: Rich descriptions and understanding of lived experiences, perceptions, cultural contexts, and social dynamics.

3. Examples

Field	Example
Health Sciences	Exploring cancer patients' emotional experiences during chemotherapy.

Unani Medicine	Understanding patients' perceptions and satisfaction with Hijamah (cupping therapy).
Education	Studying teachers' experiences of adopting online teaching platforms during COVID-19 lockdowns.

4. Strengths

- Provides deep, detailed insights into complex social or health phenomena.
- Generates new theories and hypotheses.
- Captures contextual and cultural factors influencing behaviour.

5. Limitations

- Findings are not statistically generalisable.
- Analysis can be subjective and prone to researcher bias.
- Requires strong interpretive skills and reflexivity.

Quantitative Research

1. Definition

Quantitative research involves systematic empirical investigation using numerical data to quantify variables, test hypotheses, examine relationships, and identify causality.

2. Characteristics

- Nature: Objective, structured, measurable.
- Data: Numerical, statistically analysable.
- Sampling: Large, random sampling for generalisability.
- Methods:
    - Surveys and questionnaires
    - Experiments
    - Randomised Controlled Trials (RCTs)
    - Cohort and case-control studies
- Analysis: Descriptive (mean, SD, frequency) and inferential statistics (t-test, chi-square, regression).
- Outcome: Statistical significance, prevalence, incidence, association, or causation.

3. Examples

Field	Example
Health Sciences	Measuring the effectiveness of a new antihypertensive drug in reducing blood pressure.
Unani Medicine	RCT testing the efficacy of Majoon Dabeedulward in hepato-toxicity.
Public Health	Surveying prevalence of anaemia among pregnant women in a district.

4. Strengths

- Produces generalizable, objective findings.
- Tests hypotheses with statistical rigor.
- Allows prediction and quantification of relationships.

5. Limitations

- May overlook subjective meanings or experiences.
- Requires careful design to avoid bias and confounding.
- Less suitable for exploring 'why' behind behaviours or beliefs.

Mixed Methods Research

1. Definition

Mixed Methods Research combines both qualitative and quantitative approaches within a single study to gain comprehensive insights.

2. Characteristics

- Nature: Integrative, pragmatic.
- Data: Both numerical (quantitative) and non-numerical (qualitative).
- Designs:
- Sequential explanatory: Quantitative study first, followed by qualitative to explain results.
- Sequential exploratory: Qualitative study first to explore, then quantitative to measure.
- Concurrent triangulation: Both approaches conducted simultaneously to corroborate findings.
- Analysis: Integration of statistical results and thematic insights to derive holistic conclusions.
- Outcome: Combines breadth and depth, validates findings through triangulation.

3. Examples

Field	Example
Health Sciences	Conducting a survey on medication adherence rates (quantitative), followed by interviews to explore reasons for non-adherence (qualitative).
Unani Medicine	Testing Safoof-e-Mohazzil for obesity through an RCT (quantitative) and interviewing patients about lifestyle changes and experiences (qualitative).
Public Health	Surveying student performance statistically, and conducting focus groups to explore perceptions of a new teaching method.

4. Strengths

- Provides comprehensive understanding by integrating numbers and meanings.
- Validates results through methodological triangulation.
- Bridges gaps between theory and practice by combining general trends with individual experiences.

5. Limitations

- Time-consuming and resource-intensive.
- Requires expertise in both qualitative and quantitative methods.
- Data integration can be complex and challenging to interpret cohesively.

V. Comparative Summary Table

Aspect	Qualitative Research	Quantitative Research	Mixed Methods Research
Focus	Exploring meanings, experiences, and processes	Measuring variables, testing hypotheses	Integrating both qualitative and quantitative data
Data Type	Non-numerical (words, texts, images)	Numerical (statistics, counts)	Both
Sampling	Small, purposive	Large, random	Both
Analysis	Thematic,	Statistical tests	Combined

	narrative, content analysis		(thematic + statistical)
Outcome	Theory generation, understanding experiences	Generalizable findings, cause-effect relationships	Comprehensive, validated understanding
Example	Patients' experiences of chronic pain	Effect of Unani drug on blood glucose levels	Effectiveness + patient perception of Unani therapy

Each methodology serves distinct purposes:

- Qualitative research is ideal for exploring why and how phenomena occur, generating hypotheses, and understanding contexts and experiences.
- Quantitative research tests how many, how much, or whether relationships exist, yielding statistically generalisable results.
- Mixed methods research combines both to provide robust, holistic insights essential for effective health interventions, policy making, and integrative medicine development.
- For Unani research, qualitative studies can explore patient beliefs about therapies, quantitative trials can validate efficacy, and mixed methods can integrate both to enhance clinical practice and global acceptance.

Chapter 4.
Research Design

It is a strategy which describes the methods of collection of data, its method of analysis and the way of preparation of the report. The research design reflects the objectives of the research project. The selection of the most appropriate and feasible research design is carefully done by the researcher. Its components are partly mandatory and partly a result of choices made by the researcher.

Types of research design:

There are two main types of research designs i.e. Observational research and experimental or interventional research.

Observational Research

Everyday people observe a lot of things; this mere observation can't be termed as the research. The observation becomes research when it is guided by careful planning of methods and their implementation in better ways controlling the validity and reliability. In observational research, the phenomenon to be observed occurs naturally and the researcher is keenly aware of it and takes necessary measurements but does not intervene or disturb the natural course of the phenomenon. Newton's observation of the apple falling from the tree on his head and Newton discovering the gravity is an example of observational research.

An observation in the context of research includes recording accurate measurements after keenly observing things. It is necessary that the measurements are the same even if they are recorded by different individuals. Therefore operational definitions of key concepts are used during research to make sure everyone is talking about the same magnitude of the phenomenon.

An observation can be *participant* or *non-participant* observation depending upon whether the observer participates and joins in the activity of the group being observed or not. In participant observation the investigator joins and shares the experiences of the group being observed whereas in non-participant observation the investigator does not share the experiences of the group although he may interact with the participants and explain the purpose of his observation. Sometimes the investigator observers the group but does not make his presence felt to the group being observed and hides his identity. This observation

removes any doctored behavior the participants may adapt when they know that they are being observed. This type of observation is called *disguised observation*.

Types of Observational Study: Observational study is of two types

- Descriptive study
- Analytical study

Descriptive study

When the study design is not structured formally to test the hypothesis i.e., the study is neither analytical nor experimental it is called descriptive study. This study is generally the first stage of an investigation and it aims at the creation of the hypothesis rather than testing the hypothesis.

In this study, different qualitative and quantitative techniques like interviews, questionnaires, participant's observation, statistics describing different statuses of communities, groups, situations, programs and other individual or ecological units are used in the collection of data. Analysis and interpretation of data is done to identify any association of the characteristic with the health related condition. The primary aim is to frame hypothesis which can be tested by analytical or experimental studies.

Types of descriptive study:

• Case reports

These are an essential component of descriptive research methodology, providing detailed documentation of single patient cases or small groups to illustrate unusual conditions, diagnostic processes, treatments, or outcomes. These reports serve as the initial step in building the evidence base for interventions, especially in scenarios where large-scale clinical trials are not yet feasible or for conditions unique to Unani practice.

In research methodology, case reports in Unani medicine:

- Document Unique or Novel Events: They describe rare presentations, unexpected effects, or innovative applications of Unani treatments, offering valuable clinical insights.
- Bridge Classical Knowledge and Modern Evidence: Case reports translate classical Unani concepts (such as mizaj—temperament, humours, and traditional diagnostic signs) into structured observations that can be communicated to the broader scientific community.
- Generate Hypotheses: They provide the groundwork for future research by identifying patterns or therapeutic effects that warrant further study in larger, controlled designs.

Methodological characteristics include:
- Systematic Patient Data Collection: Information about the patient's Unani diagnosis, treatment regimen, progress, and outcomes is systematically recorded, often including both traditional and modern biomedical markers.
- Integration with Observational Designs: Case reports can develop into case series, cross-sectional studies, or be combined with retrospective treatment-outcome surveys, increasing the strength and breadth of evidence.
- Focus on Descriptive Analysis: Data is typically qualitative and narrative, though modern approaches encourage inclusion of quantitative parameters to enhance objectivity and reproducibility.

Within the structure of Unani research methodology, the hierarchy of study designs begins with case reports and series, progressing to more complex observational and interventional designs such as cohort and case-control studies, randomized controlled trials, and systematic reviews. This structured approach helps maintain scientific rigor while respecting the epistemological foundations of Unani practice.

Caveats:
- Limited Generalizability: While case reports are valuable for generating hypotheses and sharing unique clinical experiences, they cannot establish causality or efficacy definitively due to their descriptive nature and lack of controls.
- Potential Bias: The subjective nature of reporting and the unique diagnostic framework of Unani medicine can introduce biases, so standardized reporting guidelines and attention to methodological transparency are crucial for scientific acceptance.

• Case series:

A case series is an observational descriptive study that systematically documents and analyzes the treatment and outcomes of a group of patients sharing a similar clinical condition, all managed according to a specific Unani approach. It represents an advance from individual case reports by offering insight into patterns across several patients, though it does not have a control group.

Key attributes and methodology of case series in Unani medicine:

- Patient Group and Condition: A case series involves multiple patients (typically more than two) who share a diagnosable condition, and whose management follows standardized or similar Unani diagnostic and therapeutic protocols.
- Systematic Data Collection: Clinical features, Unani diagnosis (e.g., mizaj/type, humoral imbalance), treatment regimen (herbal, regimenal, pharmacotherapy), and measurable outcomes are recorded for each patient, enhancing reproducibility and transparency.
- Descriptive Focus, No Control Group: Outcomes following Unani interventions (such as herbal formulas, regimenal therapies, or diet modifications) are documented, but there is no comparative group for statistical inference about efficacy, limiting the ability to ascribe causality.
- Use for Rare or Refractory Conditions: Case series are commonly used to report on emerging uses of Unani treatments in poorly-understood, rare, or drug-resistant diseases, such as chronic skin diseases, psychiatric conditions, or persistent infections.
- Pattern Recognition and Hypothesis Generation: By identifying response patterns, adverse effects, and possible therapeutic benefits, case series inform larger, more rigorous studies, and support the evaluation of traditional concepts in modern contexts.

Typical Structure:

- Description of patient demographics and diagnostic criteria (including both Unani and biomedical parameters).
- Presentation of intervention details (dose, duration, method, adherence).
- Documentation of patient response using subjective and objective measures.
- Narrative synthesis of findings, often illustrated with tables or individual patient summaries.

Examples in Unani Medicine: Published case series have investigated Unani interventions in conditions including psoriasis, major depressive disorder, flu-like syndromes, and chronic anal fissures, demonstrating feasibility and preliminary efficacy in clinical settings.

Caveats:

- They do not establish cause-effect relationships and are vulnerable to biases (selection bias, reporting bias), but they are valuable for early-stage evidence and guiding research priorities.
- Standardized reporting guidelines (e.g., CARE) are recommended to increase scientific validity.

• Community diagnosis or needs assessment:

In this kind, data pertaining to existing health problems, high prevalence, groups at risk, health programs, etc, is collected. The aim is to identify and assess the needs of the community and provide data for planning of future actions.

• Epidemiological description of disease occurrence:

This kind of study is aimed at describing the distribution and occurrence of health or disease of individuals in a population in relation to specific characteristics (age, sex, occupation, ethnicity, marital status, social class, and behavior), place (international, national, rural/urban, local) and time (epidemic, cyclic, and seasonal).

• Descriptive Cross-sectional studies or Prevalence studies:

These studies are simple, easy and inexpensive to conduct. In this study, a sample (cross-section) of a population is observed and data is collected. This helps in determining the prevalence rates and hence the study is called prevalence study. The study is carried out either over a period of time (period prevalence) or at a point of time (point prevalence).

The data can be collected regarding individual characteristics (age, sex, body weight, etc) and risk factors (physical activity, salt intake, stress, etc). Thus prevention of a disease can be planned by knowing how a disease is related to certain variables. If these studies are repeated they can fairly give information about distribution of disease, health care needs and also help in planning of the healthcare services. In many countries cross sectional studies are conducted regularly with focus on demographic and individual characteristics. Disease prevalence can be

determined with relation to age, sex, ethnicity, etc which in turn helps in healthcare planning.
There are certain limitations of prevalence studies like these studies are not useful in acute cases, they don't provide much information about the incidence rates and are nto helpful in studying the natural history of disease.

Ecological descriptive studies:

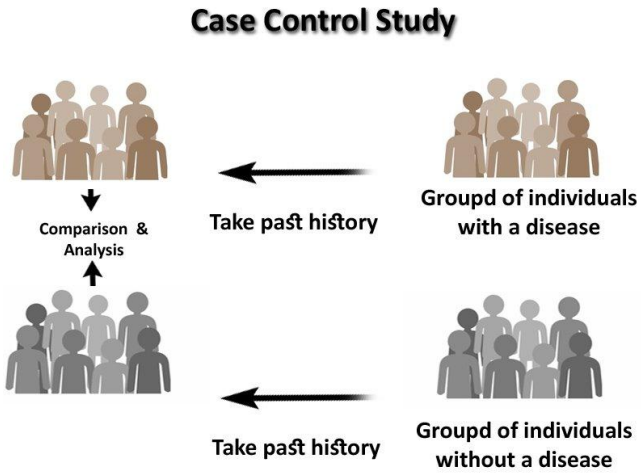
The unit under observation in this type of study is a group or aggregate rather than individuals. Existing statistics are correlated with disease prevalence/incidence in a group or population to note trends of factor. For example, in France 2003, increasing death rate was well correlated with heat wave although increasing air pollution played a role as well. Thus Ecological studies are easy to conduct but the data collected is difficult to interpret. Moreover the data is related to a group so it cannot determine exposure and effect relationship at individual level.
Although descriptive studies don't aim at testing hypothesis some kind of testing is done in ecological and cross sectional studies.

Analytical Research

An observational research study which aims at establishing relationship between an outcome (disease) and a risk factor (etiological agent) is called analytical research. Thus the aim is to test the hypothesis rather than formulating it. Analytical study is of two types

a. Case Control Study
b. Cohort Study

Case Control Study: Also called as retrospective study, case control study is the simplest and the most commonly used analytical study. The exposure to suspected risk factors and disease (stated in the hypothesis) has already happened even before the study started. The study goes back in history and makes analysis.


Case Control Study
Comparison & Analysis
Take past history
Groupd of individuals with a disease
Take past history
Groupd of individuals without a disease

Firstly, two types of groups are used i.e. case and control group. The group of participants having the disease is called case group and the group containing participants not having the disease but is similar to the case group with respect to age, sex, marital status, occupation, social status, etc is called as control group.

Data regarding the exposure to suspected risk factor in cases and controls is collected separately by interview, questionnaire and/or from the records. Collected data is analyzed to notice whether the exposure rate is more among the cases then it is said that there is an association between the disease and the risk factor.

For example, if hypothesis is stated as “Chewing tobacco causes oral cancer”, then two groups i.e., those having oral cancer (cases) and those not having oral cancer (controls) are selected. Information about exposure to tobacco chewing is collected and if the frequency of exposure is more among the cases then it is said that there is an association between tobacco chewing and oral cancer.

Steps in conduction of case control studies:

1. Selection of cases and controls
2. Measurement of data on exposure
3. Analysis

1. Selection of cases and controls:

Selection of cases: The definition of case should be made prior to the study as per diagnostic and eligibility criteria and the stage of the disease. Generally newly diagnosed cases within a period of time are considered eligible for inclusion since old cases may have risk of complications involved.
The source of cases is usually the hospitals because the records can be conveniently obtained. Sometimes cases are selected from the general population as in population based study.

Selection of controls: As already stated, controls are groups of people who are similar to cases but are free from the disease being studied. They serve as comparison group while evaluating results. When selection of control group is not done properly the results of the study will become invalid. Selection of control may present difficulties like if the disease being studied has sub-clinical states then the selection will be invalid.

The sources of controls can be patients with difference disease from the hospital where cases were selected; or relatives or neighbours of the cases or a sample from the general population. Sometimes more than one control is selected to remove the bias that may arise while having only one control group.

Confounding factor: It is very important for the participants to be free from the factor which is known to be associated with disease or associated with risk factor being studied or it can itself act as risk factor

for the disease. This factor is called as confounding factor. It can ruin the study by distorting the results. For example, if we are studying relationship between lack of physical activity and weight gain then dietary intake can be confounding factor as it can also affect weight gain.
Confounding factor can of two types based on the type of bias it causes; firstly it can be positive confounding factor i.e., it can overestimate/amplify the effect. In the case of the above cited example, diet can cause weight gain acting as positive confounding factor. Second type is negative confounding factor i.e., it can underestimate/ decrease the magnitude of the actual effect.

Matching: It is a common method applied to select controls in such a way that control have characteristics similar to cases but are free from confounding factor. The aim of matching is to remove confounding factor and make sure that there is comparability between cases and controls. Matching also improves the efficiency of the study.
Matching is usually done by selecting controls that are similar to cases with respect to age, sex, race, socio-economic status, etc. Matching of the suspected risk factor should be avoided because this will eliminate its role in studying the etiology.

Types of matching:
Paired Matching:
Each control is selected in such a way that it resembles the corresponding case with respect to different characteristics. It is also called as individual or one to one matching. The controls may be selected siblings, friends, colleagues, etc. For example, a 65 year old worker may be matched with his colleague who is 65 years old. It is difficult to find individual match for each case and more over it is not suitable to use one to one matching while controlling two or more variables.

Group or stratified Matching:
In this type, instead of matching the controls individually they are matched in groups. Firstly, the cases are assigned to subgroups based on age, sex, etc, and then the control groups are matched with the assigned subgroups.

2. Measurement of data on exposure:

Data is collected among the cases and the controls regarding the frequency and duration of exposure using interview methods, questionnaires, records, etc. Criteria for measurement are defined and used for measuring exposure.

3. Analysis

It is important to analyze the collected data,

- to find whether there is any association between disease and suspected risk factor by calculating "exposure rate";
- to know the strength of association between disease and suspected risk factor by calculating "Odds ratio" and
- to know whether the relation between disease and suspected risk factor is statistically significant or not by applying Chi square test to calculate P-value (the probability of association between disease and risk factor)

Cohort Study

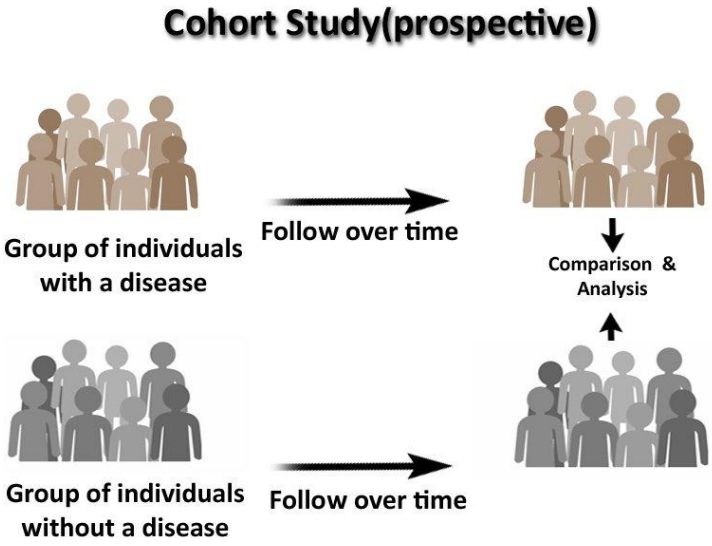
Also called as prospective study or forward looking study or longitudinal study or incidence study, cohort study is a type of analytical study. The main aim of the study is to collect evidence to accept or refute association between 'the exposure to the suspected factor and the outcome' which are stated in the hypothesis.

What is a Cohort?

A cohort is a group of persons having a common characteristic during a given period of time. For example: a group of post-graduate students of general medicine department are called general medicine cohort, a group of patients admitted in male medical ward 1 are called male medical ward 1 cohort. Similarly, in cohort study a group of persons having similar characteristics such as age, sex, marital status, etc and are exposed to a suspected factor are called study or exposure cohort whereas another group of persons having characteristics similar to exposure cohort but are not exposed to suspected factor are called control cohort.

In contrast to case control studies, the outcome has not yet occurred at the commencement of the study, but in retrospective cohort study the outcome has occurred at the start of study.The cohorts

are selected before the start at a point of time when the exposure has occurred but they are free from the outcome.



Indications or uses of Cohort study:

i. Cohort studies are often used in finding health hazards associated with occupational and environmental exposure i.e.,when the exposure is rare but the incidence is high among the exposed. It is indicated when the evidence of association between exposure and outcome is available from clinical & descriptive studies.

ii. Since cohort study finds more than one outcome of an exposure it is used in studying the spectrum of disease. It can also help in studying the natural history of disease.

iii. Cohort study is used when the participants are co-operative, stable and the funds are adequate because the cohort study takes years to decades for collection of evidences regarding the exposure and the outcome.

Types of cohort studies:

1. Prospective cohort study: This study begins with selecting a sample of population having two cohort, both of them free from the

outcome/disease but equally susceptible to it. A cohort is not exposed to the risk factor i.e., control and another cohort is exposed to the risk factor. The investigator observes the cohorts over a period of time and measures the outcome.

2. Retrospective cohort study: This study is applied when the outcome has occurred and the investigator was not present to observe the cohorts. But, there is enough data available from the records allowing the investigator to collect necessary information. This study is also called as prospective study in retrospect, historical cohort study, non-concurrent prospective study. The design of the study may not allow the investigator to determine whether the cohorts were free from the outcome at the start of the study unless the outcome is death.

3. Prognostic cohort study: This is a special type of cohort study and is a combination of both prospective and retrospective cohort studies. The investigator identifies the cohorts who have been diagnosed or have received treatment at a point of time. The investigator then observes the factors which influences the outcome.

Steps in cohort study:

1. Selection of study and control cohorts: The cohort is selected from general population in a specified area if the exposure is high in them. Cohort can also be taken from special groups who are known to be exposed to the risk factor. For example, workers in an industry may be taken as the cohort. The cohort from special groups can be classified based on the degree of exposure of risk factor. These sub-groups serve as control cohorts saving the effort to select control cohort from outside. For example, those who chew tobacco less than five times a day may be taken as control for those who chew it more than five times a day. If the sub-groups are not available then controls having similar age, sex and other characteristics are selected from outside the cohort.

2. Follow up: This is done by conducting interviews, monitoring medical record, regular medical examination and performing laboratory tests at regular intervals. Usually some cohorts are lost due to change of occupation, migration, death,etc.

3. Analysis: The data is analyzed to determine presence of any association between risk factor and disease and to know the strength of association.

a. The presence of association is determined by calculating the incidence rate (frequency of the disease) in both the groups.

Cohort	Developed disease	Did not develop disease	Total
Exposed to risk factor	a	b	a+b
Not exposed to risk factor	c	d	c+d

Incidence rate = Number of new cases developing a disease/ Population at risk
Incidence rate in exposed = a/a+b
Incidence rate in non-exposed =c/c+d

If incidence rate in exposed is higher than the incidence rate in non-exposed then an association is said to exist between risk factor and the disease.

b. The strength of association is determined by estimating the following indicators: relative risk, risk difference, attributable risk, absolute risk, population attributable risk and population attributable risk proportion.

Experimental/Interventional Research

This is the best and the final step in the process of accepting or refuting a hypothesis. The conditions in an experiment are under the control of investigator who applies or removes the independent variable (treatment, risk factor, etc) and measures its outcomes. In other study designs the investigator does not have control over the conditions of the study.

Animal experiment

Animals have helped human beings in understanding anatomy, physiology, pathology and many other sciences. Galen used to dissect monkeys whenever he faced any problem in understanding the anatomy of various organs or when he wanted to know the pathology of diseases. Webester, Topley, Wilson and Greenwood carried out experiments on animals to study immunity by inducing epidemics in laboratory conditions. In this way, diseases actually occurring in human beings were reproduced in animals to study the etiology and pathology.

The experiment on animals should be done in accordance with the provisions of "The Prevention of cruelty to Animals Act, 1960" and "Breeding of and experiments on animals on (Control & Supervision) rules of 1998, 2001 and 2006". CPCSEA a statutory body established by Indian parliament under the chapter 4 section 15(1) of "The Prevention of cruelty to Animals Act, 1960" enforces the control and supervision rules. The institution planning to conduct research on animals should get itself registered with CPCSEA. CPCSEA authorizes registrations to establishments conducting experiments on animals and breeding them for the same. It conducts inspections and approves animal house facilities and gives permission for conducting experiments on animals. It takes action against those establishments which are found to violate the legal norms.

The power to approve conduction of experiment on small animals was given to Institutional Animals Ethics Committee (IAEC) after an amendment in Rules for Breeding of and Experiment on Animals (Control & Supervision) in 2006. The CPCSEA shall be consulted for approval only for conducting experiment on large animals.

Human Experiment

The ultimate method of health research is to perform an experiment on human beings. Considering the great value of human life, several precautions have to be taken while conducting a health related experiment on human beings.

Ibn e Seina's seven conditions for conducting experimental study:

First condition: Intervention should be free from temporary and external effects.

Second condition: The participant should be free from diseases other than that under study.

Third condition: Experiment should be done on participants of different temperaments.

Fourth condition: Temperament of intervention should be known experimentally.

Fifth condition: The delayed or late effects and first or early effects should not be neglected.

Sixth condition: Permanent effects should be noted

Seventh condition: Final step of experiment should be on human body.

Randomized Controlled Trial: This is considered as the most powerful way to determine the safety and efficacy of a new intervention. The participants are randomly allocated into study and control groups. The study group receives a specific intervention whereas control group or comparative group may not receive any intervention or may receive a standard practice or the best treatment or a placebo. The outcome in the study group is compared with the outcome in control group and the effects of intervention are estimated.

Types of RCT:

I. Randomized controlled clinical trial: (NTRUHS-November 2016) The most common clinical trial conducted is therapeutic trial involving drugs. Although other types of clinical trials such as diagnostic, prophylactic, trial evaluating devices, regimens, protocols are also performed.

II. Field trial: This type of trial involves participation of the healthy individuals in contrast with the clinical trial which involves participation of sick individuals.

1. Preventive trial: This type involves trial of primary preventive measure i.e. the preventive measure are applied even when the onset of disease has not occurred (For example: vaccinization). The trial usually involves large number of participants for longer periods of time. The analysis of the trial should mention benefits of the trial to the community, any risk associated and resources to the health like money, man power and material resources.

2. Risk factor trial: When one or more risk factors of a disease are identified, the investigator with the aim of hindering the development of disease modifies/eliminates the risk factor. Depending upon the number of risk factors targeted the trial can be single factor or multiple factors trial.

3. Cessation experiment: A habit or a factor suspected to be associated with the development of disease is terminated and the effect of this is evaluated.

III. Community trial: An entire community rather than the individuals is manipulated and the effect is observed.

Conducting a RCT:

a. Specifying a protocol: RCT begins with clearly stating the aims and objectives of the trial, details about sampling, randomization, intervention and controls and analysis. The protocol should be strictly followed throughout the study.

b. Selecting reference population (unit of study): The reference population is the population from which the participants are drawn. The results after the analysis are generalized to the reference population.

The participants must be randomly drawn from the reference population so that they are representatives of the reference population; informed consent must be taken from the participants; the participants must be eligible for the study and they must get benefited from the study.

c. Randomization:

In order to remove bias, matching is commonly done during analytical studies. By performing the matching only the known factors can be matched therefore to allocate all the known and unknown factors equally among the study group and the control group randomization is done. This is a procedure of distributing participants into the

experimental and control group randomly in which every individual has equal chance of being selected.

By performing randomization comparability increases i.e., the chances that both the groups are similar with respect to all variables except the intervention increases and hence the investigator can bear the confidence that the observed result is due to intervention and not due to any other factors. The investigator does not have control over randomization therefore the selection bias is removed.

Types of randomization: *1. Simple Randomization:* In this type, the random allocation of participants is done in a single sequence. A number of methods are used for performing this, for example: a coin may be tossed if its head then the participant goes to the intervention group, if its tails then the participant goes to control group; throwing a dice, if the number is below three then the participant goes to intervention group, if the number is above then the participant goes to control group; random numbers table or computer software may also be used for doing simple randomization.

This method is simple and most commonly used but when the sample size is very small performing this method may result in unequal division of participants into groups.

2. Block randomization: This method randomizes participants such that the groups have equal number of participants. The researcher firstly determines the size of a block which is in multiples of the number of group. For example, if the number of groups are two the block size can be four or six or eight. After determining size of the blocks, all the possible combinations of assignments of participants in blocks are estimated then the blocks are randomly assigned among groups.

With this type of randomization the size of the groups is balanced but the groups may have less comparability i.e. some characteristics of participants in one groups may not match with that of other group.

3. Stratified randomization: With this method balance regarding covariates is attained. The researcher identifies different covariates and makes blocks for them then assigns participants into the blocks. When all the participants are assigned into block, simple randomization is done to allocate participants into groups.

Stratified randomization becomes difficult to implement when there are many covariates or information about the covariates is not available before randomization.

4. Unequal randomization: When there is cost difference between the manipulations done on the experiment group and the control group then more number of participants may be randomized into cheaper treatment group. A randomization ratio of atleast 2:1 may be applied so that the statistical power of the study is not greatly affected.

Balance: This refers to the similarity obtained after randomization between the treatment group and the control group regarding various important factors. The only difference between the two may be that the treatment group receives the treatment and the control group does not.

d. Manipulation: After performing the randomization, the intervention is either applied or removed in the study group. The intervention could be a drug, a treatment regimen, a device, a surgical procedure, diet, exercise, a change of lifestyle, a rehabilitation procedure, a counseling method, a risk factor, a hospital service, a community approach, a health personnel, etc.

Depending upon how the control group is monitored during the manipulation stage, the control group is divided into six types by FDA.

i. Placebo concurrent control: The participants randomly allocated in the trial receive either the treatment or the placebo. The word *placebo* is taken from Latin; it means “I shall please”. It was used for people who were hired to mourn at funerals as substitutes of family members of the deceased. In the context of RCT, the placebo is a substitute of the treatment mimicking every physical characteristic of the treatment. It may provide relief from the symptom if not cure the disease. Placebo could be sugar pills in oral drug trial, distill water in parenteral drug trial, ultrasound in pressure ulcer treatment, sham traction for the cervical spondylosis treatment. These are pure placebos whereas an impure placebo is that which has some pharmaceutical effect but its use for the purported condition is not yet proven.

The participant believes that the placebo is nothing but the treatment. Hence the placebo may induce an effect psychologically

rather than therapeutically. This effect is called as placebo effect. Various researchers have tried to determine the personality traits of participants who get benefited by placebo treatment. They found few traits associated with placebo effect but the same traits were not found to be associated when the study was replicated in different individuals.

Ethical issues: The use of placebo controlled trial has been controversial. Questions have often been raised about the different aspects of the placebo. Does the placebo really produce significant results clinically? Is the placebo effect significant without deception?

It is considered ethical to use placebo controlled trial based on international guidelines when (1) no standard effective treatment exist for the disease taken up for study (2) not giving any treatment in the condition does not pose considerable risk to the participants (3) using the placebo is supported by methodological reasons and placebo does not cause any serious risk the participants (4) using the placebo is supported by methodological reasons and the aim is to develop intervention for the population from which the sample is drawn.

ii. No treatment concurrent control: The randomly assigned control group does not receive any treatment. It is obvious that the participants know that they are not assigned to treatment group i.e. they are not blind.

iii. Dose response concurrent control: Different fixed dose groups are created and participants are randomized into these groups. The participants may be given the fixed dosage initially and later the dosage may be increased. The comparison between them is done only on the final dose.

iv. Active (Positive) concurrent control: The participants randomly assigned to the control group are given an active treatment in this type.

v. External control: In external control trial, rather than using the control group of randomly assigned participants from same population a group external to the study population is used as control. The external group may have received a treatment in the past or may be receiving a treatment at a different centre.

vi. Multiple control groups: Researchers often use more than one control groups for making the comparison. There can be an active control group and a placebo control group or different dosages of test drug or active control with a placebo or without it. Thus the study becomes more significant and bears more advantages like determining the relative potency and matching active drug comparisons.

e. Follow-up: After certain define intervals of time the participants of both the groups are examined in a standard way. Some participants may be lost from the study due to death, migration, etc. This is called as attrition and it poses threat to the power of the study.

f. Assessment of outcome: The outcome could be assessed as positive results and negative results. Positive results implies that the intervention is effective and safe whereas the negative results mean that the intervention is not safe or hazardous or both.

g. Reporting: The rules of writing report are mentioned in the respective chapter of this book.

Blinding: This is a method through which either the participants or the investigator or both of them and the statistician are prevented from knowing any details about the intervention. When any level of blinding is not done the trial is called open RCT. Blinding is of three types.

Single blind:

In this type, the participants are not aware of the intervention and they do not know whether they belong to the study or the control group. Single blinding is also said to be done when either the participants or the investigator but not both of them are blind.

Double blind: In this type, both the participants and the investigator are blind and the intervention is coded. The statistician is not blind and decodes the intervention before performing analysis. This is the most common type of blinding done.

Triple blind: In this type, all the participants, the investigator and the statistician are blind.

Types of study design in RCT:

Parallel: In this, the participants are randomly allocated into study and control groups and each participant remains in the same allocated

group till the completion of the study. This design can be completed in shorter duration but with larger number of participants.

Cross-over: The participants are randomly allocated into study and control groups. Both the control group and study group are manipuated. After certain period the manipulation is stopped in both allowing a washout period so that the effects of the manipulation cease. Then the study group is treated as control group and the control group is treated as study group. Thus ever participant acts as his own control. This design can be completed with smaller number of participants but requires larger duration.

Factorial design: Sometimes it is required to study the effects of two or more independent variables on dependant variable. Thus, a factorial design is applied wherein two or more interventions are given simultaneously to the intervention group and the control group is given another intervention or a placebo. The combined effect of two interventions is compared with the control group.

Preclinical Design in Unani Medicine

In the contemporary era, integrating evidence-based scientific research with traditional Unani principles has become increasingly important to validate the safety, efficacy, and mechanisms of Unani formulations for wider global acceptance. Preclinical research designs—namely in situ, in silico, in vivo, and in vitro—play a pivotal role in this scientific validation process.

The Preclinical Research Landscape in Unani Medicine

Preclinical studies in Unani typically precede human clinical trials. The aim is to determine the pharmacological action, safety, and potential toxicities of medicinal substances. Modern Unani research institutions utilize a multi-tiered approach, involving classical (traditional) observations and practices in conjunction with advanced experimental methodologies mirrored after mainstream biomedicine.

Below, we delve into preclinical research approaches from a Unani medicine perspective.

1. In Situ Studies in Unani Research

In situ studies involve observation or experimentation on formulations, cells, or tissues in their original place or natural context. In the context of Unani medicine, in situ approaches are often employed to observe the direct effects of a formulation (like a decoction or ointment) on affected tissues or the application of remedies directly at the disease site.

Features of In Situ Preclinical Research

- Herbal applications directly on tissues or skin: For Topical Unani remedies, anti-inflammatory or wound healing effects are assessed by direct application onto animal or human tissues (post-excision), maintaining a context close to the natural biological environment[3].
- Assessment of tissue-specific responses: Changes like tissue repair, inflammation modulation, or cellular response are observed without systemic influence.
- Relevance: In situ studies simulate the traditional usage patterns of Unani formulations, often preceding further in vivo examinations.

Example:

A classical Unani anti-inflammatory cream, formulated with ingredients like Iklilul malik and Babuna, is directly tested on inflamed animal skin patches to observe reductions in inflammation or tissue irritation, mimicking the real-life usage of such pastes and creams.

2. In Silico Methods: Digital Simulations and Unani Medicine

In silico studies refer to computer-based simulations and computational analyses. Unani research has increasingly employed molecular docking, molecular dynamics, and pharmacophore modeling to predict the interaction of Unani phytochemicals with specific molecular targets, thus bridging tradition with modern molecular science.

Features of In Silico Preclinical Research

- Molecular Docking of Unani Compounds: Individual phytoconstituents from traditional Unani formulations are virtually tested for affinity and binding to disease-relevant biological targets (e.g., viral proteins, enzymes).
- Computational Screening: Large databases of phytochemical structures are screened for potential activity, expediting the candidate selection process.
- Simulation of Pharmacokinetics: Computational models can predict absorption, distribution, metabolism, and excretion (ADME) profiles of Unani medicines, guiding future in vitro and in vivo evaluations.

Example:

The Unani formulation Tiryaq-e-Wabai has been computationally screened for its ability to bind and inhibit SARS-CoV-2 targets, highlighting key phytocompounds (e.g., crocin from saffron) as potentially active constituents. Molecular dynamics simulation further validates the stability and strength of these interactions.

3. In Vivo Preclinical Studies in Unani Medicine

In vivo research is essential for understanding the systemic and holistic impact of Unani formulations within a living organism, often rodents such as mice or rats.

Features of In Vivo Preclinical Research

- Pharmacological and Toxicological Evaluation: Unani drugs or formulations are tested in animal models to assess therapeutic

properties (anti-inflammatory, hepatoprotective, antipyretic, etc.) as well as acute, subacute, and chronic toxicities.
- For instance, Khamira-e-Banafsha underwent a 90-day repeated dose toxicity study in rats following OECD guidelines, with close monitoring of mortality, clinical signs, body weight, and feed consumption.
- Efficacy Models: Exploring therapeutic effects in induced disease models (e.g., anti-diabetic activity in streptozotocin-induced diabetic rats).
- Holistic Outcome Measures: Assessment often encompasses not just disease endpoints but also parameters in line with Unani principles, like changes in temperament (mizaj), humoral balance, and physical vigor.
- Ethical Compliance: Modern Unani research adheres to institutional and governmental guidelines on animal experimentation, ensuring humane treatment and reliable data.

Example:
Preclinical studies at major Unani research institutes have reviewed Qurs-e-Mubarak and other classical formulations for safety, efficacy, and pathophysiological effects, informing subsequent clinical studies.

4. In Vitro Approaches: Cell and Tissue-Based Research

In vitro studies are conducted outside a living organism, using isolated organs, tissues, or cell systems. Their relevance grows as Unani pharmacology advances towards mechanistic elucidation and standardization.

Features of In Vitro Preclinical Research
- Bioactivity Screening: Unani formulations are assessed for antioxidant, anti-inflammatory, and cytoprotective effects using biochemical assays.
- Example: Arq Kasni, Arq Gulab, and Arq Shahtara were tested for in vitro anti-inflammatory and free-radical scavenging action using assays such as DPPH radical scavenging and heat-induced hemolysis models.
- Cell Culture Assays: Unani compounds are tested for their effect on cell viability, apoptosis, and proliferation in cultured mammalian cell lines.
- Mechanistic Insights: In vitro assays help uncover possible molecular mechanisms (e.g., enzyme inhibition, signal modulation) that underpin observed in vivo and traditional effects.

Example:

A formulated Unani anti-dermatophytic cream was evaluated for antifungal action against clinical pathogens through direct application to fungal cultures. Parallel in vivo and in vitro approaches validated the efficacy for candidal skin conditions.

Integrative Preclinical Design: Strengths and Challenges in Unani Medicine

The preclinical pipeline in Unani research increasingly involves:

- Screening via in silico and in vitro methods: Early filtering and hypothesis generation.
- Validation with in situ and in vivo studies: Confirming efficacy and safety within tissue and systemic environments.
- Relevance to holistic theory: Not merely targeting isolated biomarkers, but integrating Unani concepts such as temperament, humoral balance, and dietary influence into endpoint measurements.

Innovative Aspects

- Interdisciplinary Collaboration: Unani research institutes collaborate with molecular biologists, pharmacologists, and computational scientists, reflecting innovation and methodological soundness.
- Adherence to Standards: All preclinical research is conducted in line with international (OECD), national (AYUSH), and institutional guidelines on safety and ethics.

Ongoing Challenges

- Standardization of Herbal Drugs: Variability in the composition and quality of Unani drugs complicates reproducibility.
- Holistic Outcome Measures: Bridging traditional endpoints (temperament, humoral correction) with conventional biomedical metrics warrants further development.
- Need for Greater In Silico and Molecular Studies: While in silico approaches are advancing, further development is required for Unani formulations as complex mixtures, rather than just isolated principles.

Conclusion

Preclinical design in Unani medicine combines ancient healing wisdom and holistic paradigms with the rigor of modern science through a process that integrates in situ, in silico, in vivo, and in vitro methodologies. Each approach provides unique strengths: in situ

maintains context, in silico accelerates discovery, in vivo ensures systemic validation, and in vitro uncovers mechanistic action.

This multidimensional strategy not only affirms the pharmacological value of Unani formulations but also modernizes quality, safety, and clinical viability, ensuring that the rich Unani tradition can continue to contribute to global healthcare in evidence-based ways.

What is Clinical Research?

Clinical research is a branch of research science that establishes the safety and efficacy of specific health practices and medical products. The majority of modern knowledge about the safety and efficacy of medication, devices, diagnostic products and treatment regimens has been obtained from clinical research. This type of research is intended to provide knowledge on important health care queries. The intervention in a clinical trial may include: drugs for prevention, treatment or palliation; clinical devices, such as intrauterine devices; surgical procedures, rehabilitation procedures; medical counselling; diet, exercise, change of other lifestyle habits; hospital services, e.g. integrated versus non-integrated, acute Versus chronic care; risk factors; communication approaches, e.g. face-to-face communication Versus pamphlets; different categories of health personnel, e.g. doctors versus nurses; treatment regimens, e.g. once-a-day dispensation versus three times a day

Need for Clinical research

In clinical research, evidence is collected to establish ethical and scientific quality standards for the treatment whereas in clinical practice established treatments are used. In fact for a drug or treatment method to be used in clinical practice it must be approved through rigorous clinical research methods. It can be stated that it is unethical to bring into practice a drug or treatment method which has not passed conventional clinical research methods.

Therefore, before introducing healthcare or medical products into the market or before incorporating them in the public health programs they must pass through the spectrum of investigation to evaluate their safety and efficacy. These investigations also decide the parameters of dosing, potency, toxicity and field conditions of the drug or treatment methods. Finally complete information about the therapeutics indications, modes of administration, dosage, contraindications, warnings, safety measures, precautions, interactions, effects in target populations and safety information is documented.

The process of Clinical Research:

Clinical research is often conducted through randomized controlled trials which forms the foundation of evidence based medicine. It is the most commonly used research strategy in health based research to test

safety and measure efficacy of a drug or regimen. The following are the common clinical trials conducted:
a. prophylactic trials, e.g. immunization, contraception;
b. therapeutic trials, e.g. drug treatment, surgical procedure;
c. safety trials, e.g. side-effects of oral contraceptives and injectables;
d. risk-factor trials, e.g. proving the etiology of a disease by inducing it with the putative agent in animals, or withdrawing the agent (e.g. smoking) through cessation.

Phases of clinical trial:
The following are the various stages or phases in the process of clinical research starting from its inception to the introduction in the market and beyond that.

Phase I clinical trial (Human Pharmacology) : After a considerable pharmacological and toxicological research on experimental animals establishes that the new drug or method is safe for human use, the new drug or method is estimated for use in man. Phase I of clinical trial is usually carried out on a group of healthy volunteers. The trial could be done on both healthy males and females, provided female has completed her family and does not wish to have children in the future. The aim of this non therapeutic trial is to determine the safety of the new agent; decide the maximum dose that can be tolerated; determine the adverse reaction. The volunteers are usually admitted on research beds and are kept under close observation. The trial commenced by giving the dose from lowest to highest in cohorts of volunteers to avoid serious effects of high dosages.

After receiving the decided dose, the volunteers are monitored and the effects of agent on body functions like hepatic, renal, cardiovascular, gastrointestinal and endocrinal functions are measured through biochemical, pharmacological, endocrinological and various other investigations. There should be adequate facilities like resuscitation unit or intensive care unit in the institution to arrest any adverse reactions immediately.

Phase II (Therapeutic Exploratory Trials): (KNRUHS-Dec 2017)This phase is carried out on larger group of volunteers who are selected according to strict inclusion criteria. In the phase I the range of doses was determined, in this phase the aims are to evaluate whether the

drug has any biological activity or effect; to determine the effective dose range and further assessment of the safety. Until this phase, the knowledge regarding dose-response relationship of the drug is inadequate; therefore several ranges of doses are given in four to five interventions. The design of this phase is dependent upon the merit of phase I and this phase will decide the design of the phase III trial. This phase is conducted in 3-4 centers and the help of clinical pharmacologist as co-investigator is generally advisable.

Phase III (Therapeutic Confirmatory Trials): As the name itself suggests, the aim of this phase is to confirm efficacy and safety of the drugs (whose therapeutic activity was determined in phase II) in comparison with a standard and/or a placebo drug. This is done by obtaining adequate data from larger number of participants in multiple centers. The participants may be of either sex who are selected according to strict inclusion and exclusion criteria. This phase is usually the one reported in research journals and referred to as 'clinical trial'. The implication of larger groups of participants helps in further evaluation of dose-response relationship of the drug.
It requires great epidemiological and clinical skills and a great deal of help from laboratories to perform this phase. Prior planning, adherence to strict protocol and close monitoring are required to maintain record keeping, supervision and follow up. The guidelines in this phase are very strict because the results from this phase are evaluated by pharmaceutical agencies for manufacturing the drug or the device.

Phase IV: Customarily, the drug or the device is approved for manufacturing after the phase III, but long term adverse effects are not evaluated in phase III since it is time limited, therefore World Health Organisation and governments of various countries have shown inclination towards inclusion of another phase i.e., phase IV. The aim is to collect information regarding adverse reactions resulting from long term usage under normal field conditions. If any adverse reactions are found they are reported to Ethics Committee and correlated with toxicological data obtained in animal studies for drawing markers to alarm future warnings regarding potential adverse effects.
Late clinical phase even if conducted on thousands of participants approved drugs or devices that will be used by millions; hence this

phase requires high skills in research, epidemiology and biostatistics to ensure the accuracy and efficiency of the results.

Quasi experimental design:

Quasi experimental design is also called as non-randomized trial or non-experimental design, pre-prost intervention study. Unlike experimental design, the participants are not assigned randomly in this design. Although random allocation provides higher comparability and more reliable results, but it is not always feasible to perform randomization due to ethical or logistical reasons. For example, an experiment cannot be conducted to establish causal relationship between smoking and lung cancer or between alcohol intake during pregnancy and fetal defects. It will be unethical to apply smoking or alcohol as intervention; instead the individuals who smoke cigarette, drink alcohol have to be selected as participants in these studies. Similarly, when the frequency of disease is less and its natural history prolong then experimental study will not be feasible due to cost and logistical issues.

Since randomization is not performed in quasi-experimental study the internal validity is affected and the results are not considered much reliable. In spite of this, a lot of information in public health is based on results from quasi experimental studies. The easy availability of clinical data from hospitals is one of the reasons that quasi experimental design is performed often.

Uncontrolled trials: There is no control or comparison group in the trial and the participants are directly given the intervention and are observed for the outcome. There is no assurance that the effect is due to the intervention; hence the study is not useful in deciding the efficacy of the intervention. Nevertheless, it may be used to find out the effective dose, the adverse effects and the safety of a new intervention when there are no controls available (such as in rabies where the mortality is 100%).

In uncontrolled studies, historical cohorts may be used as controls, but the experts believe that using historical cohorts may over-estimate the efficacy of an intervention. The best possible way to estimate the efficacy remains the RCT.

Natural experiment: There are certain naturally occurring circumstances which cannot be created for the sake of experimental

study, but when they occur naturally they are identified and studied as natural experiment. Examples include earthquakes, floods, effect of acute stress on cardiovascular mortality, relationship between smoking and lung cancer.

Before and after comparison studies: These are community trials in which the efficacy of an intervention (eg: preventive measure, etc) is estimated while the group receiving the intervention is itself used as control group. For example: after the seatbelt legislation was passed in Victoria, Australia there was fall in number of injuries and deaths in car accidents.

Sometimes, instead of using the treatment group as control, natural control group is used. It is the group which is created out of natural circumstances. For example: a community receiving intervention may be compared with another community similar to it.

Meta-Analysis and Systematic Review

Systematic reviews and meta-analyses are rigorous methods for synthesizing clinical research, now considered gold standards for evidence-based practice across the sciences and increasingly within traditional systems like Unani medicine. Their role has grown in importance as researchers strive to establish the safety, efficacy, and scope of Unani interventions for broader acceptance and integration into modern healthcare systems.

What Is a Systematic Review?

A systematic review is an in-depth, methodical summary of all available research on a specific question. Its process is:

- Structured and Reproducible : It follows a predefined protocol, such as the PRISMA (Preferred Reporting Items for Systematic Review and Meta-Analyses) guidelines, ensuring each step—from literature search, inclusion/exclusion criteria, to data extraction—is systematic and transparent.
- Comprehensive : Aims to identify all relevant studies (published or unpublished), minimizing bias.
- Critical Appraisal : Each included study is assessed for quality and risk of bias, using standardized tools.
- Data Synthesis : Results of individual studies are summarized, often qualitatively, and patterns of evidence are highlighted.

Unani Example

A systematic review of Unani medicine's use in neurodegenerative disorders involved screening classical texts as well as electronic databases, applying rigorous inclusion criteria grounded in both classical symptoms and modern diagnostic frameworks. The review identified numerous single herbs and compound formulations, providing a comprehensive summary regarding their evidence basis and reliability.

What Is a Meta-Analysis?

A meta-analysis is a statistical technique that combines quantitative results from multiple studies addressing the same research question. It is usually conducted as part of a systematic review but can be a standalone analysis.

- Quantitative Aggregation: Effect sizes, such as mean difference or risk ratios, from all included studies are mathematically pooled, providing a more precise estimate of an intervention's efficacy or harm.
- Assessment of Heterogeneity: Evaluates the consistency or variability among study findings. Statistical tests (e.g., I^2 statistic) measure heterogeneity and inform the method of pooling results (fixed-effect vs. random-effects model).
- Additional Analyses: Sensitivity, subgroup, and publication bias analyses may be included to enhance reliability.

Unani Context

While more common in biomedical research, meta-analyses are gaining ground in evaluating Unani treatments. When studies on Unani interventions for a condition (e.g., COVID-19 outcomes, neurodegenerative disorders) provide comparable outcome measures, meta-analysis can offer pooled effect size estimates, strengthening claims regarding efficacy and safety.

Key Stages of a Systematic Review and Meta-Analysis

Stage	Explanation
Formulating the Research Question	Clear, focused question based on clinical or public health uncertainty
Protocol Registration	Publishing review protocol (e.g., PROSPERO), specifying methods and criteria up front
Literature Search	Comprehensive search of multiple databases using predefined keywords and criteria
Study Selection	Applying inclusion/exclusion criteria (e.g., population, intervention, outcomes, study design)
Data Extraction	Extraction of relevant data (e.g., sample size, interventions, outcomes, quality indicators)
Quality Assessment	Using tools like Cochrane Risk of Bias to evaluate methodological quality
Data Synthesis	Narrative synthesis for heterogeneous

(Qualitative/Quantitative)	findings, or meta-analysis for quantitative pooling
Reporting	Structured presentation of results, limitations, implications, typically following PRISMA guidelines

Strengths and Unique Contributions

- Objectivity and Reproducibility : Methodical approach limits subjective bias—essential for traditional medicine evidence such as Unani, where anecdotal evidence has historically dominated.
- Power and Precision : By pooling data, meta-analyses increase statistical power, making it more likely to detect genuine effects (or lack thereof) regarding a treatment or intervention.
- Identification of Knowledge Gaps: Systematic evaluations expose where evidence for Unani medicine is robust and where further research or higher-quality trials are needed.
- Guidance for Clinical Practice and Policy: They inform government, health policy makers, and practitioners about which Unani therapies can be confidently recommended—or not.

Practical Examples in Traditional Medicine

- A systematic review and meta-analysis of herbal and nutritional interventions for premenstrual syndrome (PMS) analyzed pooled data from 15 randomized controlled trials (RCTs), demonstrating a significant reduction in PMS symptoms compared to controls. This provided strong evidence in support of traditional remedies, though some results were limited by heterogeneity and risk of bias.
- In Unani medicine, a systematic review collated clinical evidence for various single and polyherbal formulations in neurodegenerative disease, providing a comprehensive, critical, and modern evaluation of historical remedies.
- Similar methods are now used to study the real-world utilization of Unani medicine—one review systematically identified all research on awareness and utilization across India, providing public health policymakers objective data on service reach and population attitudes.

Challenges and Limitations

- Heterogeneity : Traditional medicine research often features diverse interventions, outcome measures, and study populations, complicating quantitative synthesis or meta-analysis.
- Data Quality: Many studies of Unani or traditional practice may have small samples, inadequate blinding or randomization, and variable reporting standards, which can weaken confidence in pooled results.
- Publication Bias: There is often a tendency to publish positive studies, potentially skewing meta-analysis outcomes unless rigorously accounted for.
- Standardization Difficulties: Unani medicine frequently involves individualized, multi-component interventions, making direct comparisons and aggregation challenging.
- Language and Accessibility: Many important studies are published in non-English languages or in less accessible journals, requiring comprehensive and multilingual search strategies.

Impact and Future Directions

Systematic reviews and meta-analyses are reshaping Unani research in several ways:

- Raising Standards : Promoting trial quality, transparency, and reproducibility as prerequisites for inclusion in high-quality reviews[5].
- Facilitating Evidence-Based Practice : Guiding practitioners and patients towards treatments with proven efficacy and safety.
- Integrating Traditional and Modern Evidence : Enabling synthesis of ancient textual knowledge with contemporary clinical research, positioning Unani medicine for mainstream acceptance.
- Informing Further Research : Guiding funding and research priorities by identifying areas of insufficient or low-quality evidence.

As Unani research infrastructure improves, with broader adoption of formal trial and reporting standards, the utility and

influence of systematic reviews and meta-analyses will continue to grow.

Systematic reviews and meta-analyses are invaluable tools in the scientific validation of Unani and other traditional medicines. They provide a transparent, powerful methodology for structuring existing knowledge, measuring efficacy and safety, and informing clinical and policy decision-making with a rigor previously unavailable to ancient healing systems. While methodological challenges remain, their growing application promises a stronger evidence base for the future of Unani medicine both within and beyond its historical context.

Non-conventional designs

A non-conventional design in research refers to any study design that does not follow the traditional randomized controlled trial or typical observational formats (like cohort or standard case-control studies). These designs are often developed to address specific challenges, such as complex interventions, individualized treatment, real-world variability, or ethical and practical limitations of classic designs.

Black Box Design

A black box design refers to a study or conceptual approach where the internal mechanisms or processes are not explicitly analyzed or revealed. Instead, attention is focused on the relationship between inputs (what goes into the system/intervention) and outputs (the observable results or outcomes). Researchers do not investigate or disclose the internal workings ("the box" stays opaque or "black"); instead, they infer or evaluate effectiveness based solely on measurable outcomes in response to specific interventions or stimuli.

Usage: Commonly applied in control system studies, engineering, psychology, and some areas of health research where the underlying mechanisms may be unknown, too complex, or not the focus of the study.
Advantage: Allows for practical evaluation and comparison of systems or interventions without requiring a full understanding of their internal complexity.
Limitation: Lack of information about how or why an effect occurs; only the causality between input and output is observed.

N-1 Design (N-of-1 Trial)

The n-1 design, also known as the N-of-1 trial, is a study methodology where a single individual acts as their own experimental subject. The participant undergoes multiple trial periods, receiving either the intervention or a control/placebo in random or predetermined order, often with washout periods between phases to minimize carryover effects.

Usage: Primarily in personalized medicine, behavioral sciences, and for rare diseases, to assess the effect of an intervention in one specific patient.

Design: Multiple crossover periods. For example, a patient might receive treatment A, then a placebo, and then treatment A again (an ABA design), with direct comparison of effects within that person.
Advantage: Enables high-precision assessment of treatment effect for an individual; suitable for individualized interventions when group-based evidence is inadequate.
- Limitation: Not generalizable beyond the individual studied unless aggregated across many n-1 studies.

Whole System Research

Whole system research (WSR) is an approach designed to evaluate complex, holistic, or multimodal interventions—such as those seen in traditional, complementary, and integrative medicine (TCIM)—that do not fit cleanly into conventional randomized controlled trial frameworks.

Focus: Studies the combined, real-world effect of multimodal treatments (diet, lifestyle, herbs, mind-body practices, etc.), often tailored to individual patients and conditions.
Design: May use pragmatic trials, comparative effectiveness trials, pre-post studies, n-of-1 series, case series, ethnography, and mixed-methods designs. Emphasis is given to "model validity"—ensuring that the research questions and methods fit the paradigm and complexity of the treatments being studied.
Advantage: Captures the complexity of real-world health care, including individualized treatment, patient-centered outcomes, and multi-component interventions.
Limitation: Less control over variables, more challenging to attribute outcomes to specific components, and potentially less suitable for hypothesis testing about single interventions.

Flexible-Dose Design

A flexible-dose design refers to clinical trials in which the dose of the intervention (typically a pharmaceutical) can be adjusted during the trial according to individual patient responses, side effects, or other clinical factors—more closely mimicking actual clinical practice than fixed-dose trials.

Usage: Common in psychopharmacology and trials where optimal dosing is uncertain or variable between individuals.
Design: Investigators or clinicians modify doses for patients throughout the trial period based on pre-specified criteria or clinical judgment, rather than assigning and maintaining a single dose.
Advantage: Increases trial relevance to real-world practice, allows for individualized titration, and can better assess the true benefit-risk profile of a medication in routine care.
Limitation: Introduces complexity in statistical analysis (due to dose variation and selection bias in who gets dose changes), and requires sophisticated modeling to interpret results accurately.

Summary Table

Design Type	Key Features	Main Advantages	Limitations
Black Box	Only input-output observed; inner process not described	Simple, practical, used in complex/uncertain systems	Cannot explain underlying mechanism
N-1 Design	Single participant; multiple crossover periods	Personalized, sensitive to individual effects	Not generalizable; labor-intensive
Whole System Research	Evaluates multimodal, complex interventions	Real-world relevance; holistic; model validity	Hard to isolate effects; more complex analysis
Flexible-Dose Design	Doses adapted during trial as per response	Mirrors clinical practice; more individualized	Statistical complexity; possible bias

These approaches are used when traditional designs are not suitable—such as with highly individualized therapies, multi-component treatments, ethical constraints, or complex health systems. While they

can better match real-world scenarios and allow for individualized assessment, they often come with increased analytical complexity, potential for bias, and limitations in generalizability.
Alternative terms like "pragmatic trials," "historical control studies," "case-cohort," or "nested case-control" are also considered non-conventional when they deviate from strict randomization or introduce innovative ways to handle data or population selection

Chapter 5. Research Ethics

Ethics in research related to Humans and Animals

History

Ethics in research involving humans became formalized after major abuses, notably during World War II with Nazi experimentation and the Tuskegee Syphilis Study, leading to the development of the Nuremberg Code (1947), the Declaration of Helsinki (1964), and the Belmont Report (1979) as foundational documents outlining protections for human subjects. For animals, the history traces back to the 19th century, with the UK's Cruelty to Animals Act (1876) and the US Animal Welfare Act (1966), established alongside evolving public concerns and advances in biology, to ensure humane treatment and welfare.

Need

The need for research ethics arises from the potential harm research can cause to individuals, communities, and animals. High-profile cases of unethical research demonstrated the capacity for abuse, exploitation, and suffering without clear ethical frameworks. For animals, growing public concern for welfare and scientific advances recognizing animal sentience underlined the need for regulating harm and promoting humane treatment in research.

Role

Ethics in research serves to:

- Protect human and animal welfare by setting boundaries for acceptable risk and harm.
- Promote social benefit by ensuring research is justified by meaningful advances in knowledge or health.
- Safeguard rights of participants, including informed consent and the autonomy of human subjects.
- Ensure fairness and justice, especially for vulnerable populations.
- Guide researchers in balancing competing interests: scientific progress versus welfare and moral values.
- Maintain public trust in research institutions and scientific findings.

Fundamental Principles

For human research, the widely accepted principles, as outlined in key documents (e.g., Belmont Report), are:

- Respect for persons: Recognizing autonomy and obtaining informed consent; providing additional protections for those with diminished autonomy.
- Beneficence: Maximizing possible benefits and minimizing possible harms to participants.
- Justice: Ensuring fair distribution of the burdens and benefits of research.

For animal research, fundamental principles include:

- Social benefit: Justifying animal use only if the research offers substantial, otherwise unattainable benefits.
- Animal welfare: Minimizing harm, pain, and distress; providing humane care.
- Respect for animal moral status: Recognizing sentience and moral considerations, not treating animals merely as tools.
- The classic 3 Rs: Replacement (using alternatives to animals whenever possible), Reduction (using the fewest animals needed), and Refinement (designing procedures to minimize suffering).
- Some frameworks further add respect for ecosystems in animal research to consider broader environmental impacts.

In summary, ethics in research involving humans and animals is grounded in history marked by abuses, driven by the need to protect welfare and rights, and plays a crucial role in guiding responsible, just, and humane scientific inquiry. Its fundamental principles center on respect, beneficence, justice, animal welfare, and social benefit, reflecting widely shared moral values.

Pharmacovigilance Program for Unani and ASU&H Drugs

The Pharmacovigilance Program for Unani and ASU&H (Ayurveda, Siddha, Unani & Homoeopathy) Drugs was established by the Ministry of AYUSH, Government of India, and marks a significant move towards structured and evidence-based monitoring of traditional medicines for safety issues and adverse drug reactions (ADRs). Below is a detailed integration of its history, objectives, organizational hierarchy, and ADR reporting methodology as it applies specifically to Unani medicine and related drugs.

History

Historically, ADR reporting in Unani medicine was informal—clinicians would note side effects in personal records, with no centralized mechanism for collection or analysis. The rapid integration and increased use of ASU&H drugs, combined with global focus on drug safety, drew attention to the lack of formal pharmacovigilance in traditional medicine. To address this, the Ministry of AYUSH formally launched the National Pharmacovigilance Program for ASU&H drugs (including Unani) on 29th September 2008, following expert consultations, WHO guidance, and the need to align with international safety standards. This initiative institutionalized ADR monitoring and safety evaluation, aligning traditional practices with modern public health expectations.

Objectives

The program's main objectives are to:

- Ensure patient and public safety by systematically recording, assessing, and preventing ADRs linked to Unani and other ASU&H drugs.
- Build and maintain a national database of ADRs to support evidence-based regulation and product improvement.
- Promote awareness among practitioners, regulators, and patients regarding the possible risks and safe use of these drugs.
- Detect and regulate misleading advertisements and unsubstantiated therapeutic claims for Unani and ASU&H formulations.

- Support regulatory decisions and interventions to authorize, restrict, or withdraw products based on safety evidence.

Hierarchical Structure

The pharmacovigilance program follows a three-tiered hierarchy to efficiently cover the national landscape and ensure smooth flow of ADR data:

Level	Functions & Roles	Key Institutions
NPvCC	National coordination, policy, data analysis, reporting to Ministry of AYUSH	All India Institute of Ayurveda (AIIA), New Delhi
IPvCCs	Supervise & mentor peripheral centers; regional causality analysis;data collation	National Institute of Unani Medicine (NIUM), Bengaluru (for Unani), others for Ayurveda, Siddha, etc.
PPvCCs	Frontline reporting, data documentation, practitioner/patient training, public awareness campaigns	Unani medical colleges, research institutions, teaching hospitals

Each level has defined responsibilities: PPvCCs are the point of entry for ADR data, IPvCCs provide regional expertise and evaluation, and NPvCC ensures national oversight, regulatory action, and feedback loops.

Adverse Drug Reaction (ADR) Reporting Method

Who can report:

- Healthcare professionals (Unani practitioners, pharmacists, nurses)
- Patients/consumers

How to report:

- Complete the ADR Reporting Form: Standardized forms designed specifically for ASU&H drugs.
- Submission methods: In person at PPvCCs, via postal mail, or electronically (email); digital portals are being developed/expanded for easier access.

- Reportable events: All suspected ADRs, drug-drug/herbal interactions, medication errors, defects in drug quality, and misleading advertisements.

Data flow:

- Reports are submitted at Peripheral Pharmacovigilance Centres (PPvCCs).
- Data is analyzed and reviewed for authenticity and clinical significance at Intermediary Pharmacovigilance Centres (IPvCCs).
- Summarized and escalated cases go to the National Pharmacovigilance Coordination Centre (NPvCC) for collation, national trend analysis, and regulatory guidance.

Actions on reports:

- Verified cases may trigger safety alerts, product recalls/modifications, clinical advisories, and updates to practice guidelines.
- Data informs regulatory decisions at the Ministry of AYUSH level and helps disseminate risk information to practitioners and the public.

Additional Notes

- This program fills a critical gap in the traditional medicine sector, moving away from the myth that ASU&H drugs (including Unani) are universally safe without formal vigilance.
- Efforts are ongoing to increase awareness , improve practitioner engagement, integrate digital tools, and build a culture of safety documentation in the Unani medical community.

Ultimately, the Pharmacovigilance Program for Unani medicine plays a foundational role in evolving this ancient system to meet contemporary safety, quality, and public health standards.

ICMR medical guidelines

The Indian Council of Medical Research (ICMR) medical guidelines serve as the national standard for ethical conduct in biomedical and health research involving humans in India. Below is an overview highlighting their history, purpose, role, and fundamental principles:

History and Need

- ICMR first published ethical guidelines in 1980, with major revisions in 2000, 2006, and the most recent comprehensive update in 2017 to address emerging issues and adapt to international standards.
- The guidelines ensure the protection of participants' dignity, rights, safety, and well-being, responding to the increasing complexity and responsibility of biomedical research in India.

Purpose and Scope

- These guidelines aim to uphold the highest professional and ethical standards for all biomedical and health research conducted in India.
- The guidelines are mandatory for all researchers, institutions, sponsors, and ethics committees involved in research with human participants, covering design, approval, conduct, reporting, and publication stages.

Role

- Safeguard participants from harm and exploitation.
- Promote social and scientific value while maintaining public trust.
- Ensure transparency, accountability, and integrity across all stages of research.

Fundamental Principles

The ICMR guidelines are based on four basic principles of research ethics:

1. Autonomy (Respect for persons): Protects individuals' rights to make informed, voluntary choices about participation.

2. Beneficence: Promotes the well-being of participants and aims to maximize benefits.
3. Non-maleficence: Seeks to avoid causing harm to human participants.
4. Justice: Ensures fairness, equity, and non-discrimination in the selection of research participants and distribution of benefits and burdens.

Additional General Principles Expanded in ICMR Guidelines:

- Essentiality: Human participation must be scientifically and ethically justified.
- Voluntariness and Informed Consent: Participation must be free from coercion, with clear, adequate information provided.
- Non-exploitation: Vulnerable groups must not be unfairly targeted.
- Social Responsibility: Research should not disrupt social harmony or worsen disparities.
- Privacy and Confidentiality: Protects the identity and personal information of participants.
- Risk Minimization: Actively reduce risks to participants throughout the research process.
- Accountability and Transparency: Researchers are accountable for conduct and must ensure full disclosure of conflicts of interest.
- Environmental Protection: Research should avoid harm to the environment.

Implementation and Oversight

- Requirement for review and approval by independent ethics committees.
- Emphasis on responsible conduct of research, including grievance redressal and handling of research misconduct.
- Recent updates have included guidance for integrative medicine and emerging technological and public health contexts.

Overall, ICMR guidelines are considered a benchmark for ethical biomedical research in India and inform similar efforts internationally, ensuring science progresses with respect for human rights, safety, and social values.

ICH-GCP (International Council for Harmonisation–Good Clinical Practice) guidelines

The ICH-GCP (International Council for Harmonisation – Good Clinical Practice) guidelines provide the international benchmark for ethical and scientific quality in the design, conduct, documentation, and reporting of clinical trials involving human participants. They ensure that the rights, safety, and well-being of participants are prioritized and that data generated are credible and widely accepted by regulatory authorities worldwide.

Historical Background and Purpose

- First finalized in 1996, the ICH-GCP guideline established a harmonized standard for countries including those in the EU, US, and Japan, to support the mutual acceptance of trial data and ethical protection of human subjects in clinical research.
- Prompted by historical lapses in ethical standards in clinical trials and the globalization of research, the guideline addresses scientific, regulatory, and societal needs for trustworthy, transparent, and humane clinical investigation.

Scope

- Applies to all clinical trials involving human subjects intended for regulatory submission.
- Serves as the foundation for national and regional GCP standards; adopted beyond ICH regions due to its comprehensive approach.

Structure and Key Parties

- Defines responsibilities for sponsors, investigators, monitors, and regulatory agencies.
- Establishes the overseeing role of Independent Ethics Committees (IECs)/Institutional Review Boards (IRBs), which must review and approve protocols, consent forms, and procedures to protect participant welfare.

Thirteen Core Principles

The ICH-GCP guideline is built on 13 detailed principles:

1. Ethical Conduct: Clinical trials must align with the ethical principles from the Declaration of Helsinki and regulatory requirements.
2. Risk-Benefit Justification: Trials are initiated and continued only when anticipated benefits justify risks to participants and society.
3. Subject Primacy: The rights, safety, and well-being of subjects must prevail, superseding scientific and societal interests.
4. Adequate Preclinical and Clinical Data: Sufficient background, including nonclinical data, must support the proposed trial.
5. Scientific Soundness & Protocol: Trials must be scientifically valid, grounded in a clear and detailed protocol.
6. Protocol and Ethics Review: Trials require prior approval from an IRB/IEC and must be conducted according to the reviewed protocol.
7. Qualified Medical Care: Qualified physicians or dentists must oversee medical decisions and care for participants.
8. Qualified Personnel: All trial staff must have appropriate education, training, and experience.
9. Informed Consent: Each participant must give freely obtained, informed consent before enrollment.
10. Accurate Data Management: All trial data must be accurately recorded, stored, and available for verification and reporting.
11. Confidentiality: The identity and records of subjects must be protected in compliance with privacy regulations.
12. Investigational Product Integrity: Products must be manufactured, handled, and stored per Good Manufacturing Practice (GMP) and only used as outlined in the protocol.
13. Quality Systems: Quality assurance and control systems must be implemented for all aspects of the trial.

Essential Procedures

- Investigator Responsibilities: Ensure participant safety, protocol compliance, accurate reporting of adverse events, and data confidentiality.
- Sponsor Responsibilities: Oversee trial planning, monitoring, financing, and data management; ensure mandatory quality systems are in place.
- Independent Ethics Committee/IRB: Review and approve all trial activities, monitor ongoing compliance, and safeguard participant rights and safety.

- Informed Consent Process: Provide comprehensive information on trial purpose, risks, and benefits, ensuring voluntary and autonomous decision-making.
- Data Integrity and Safety Monitoring: Establish systems for data validation, monitoring, and prompt reporting of safety issues.

Recent Updates

- Recent revisions reflect advances in clinical trial methods, risk-based quality management, and digital technologies.
- Emphasize quality by design, proactive risk evaluation, stakeholder engagement, and the proportional application of trial oversight based on risk assessment.

Significance

ICH-GCP guidelines are central to ethical clinical research, enhancing global confidence in trial results, protecting participants, and underpinning regulatory approvals and public trust worldwide.

GCP unani guidelines

The Good Clinical Practice (GCP) guidelines for Unani medicine—under the umbrella of AYUSH (Ayurveda, Yoga & Naturopathy, Unani, Siddha, and Homoeopathy) and explicitly detailed in the GCP-ASU document—establish the ethical and scientific framework for conducting clinical research and trials involving Unani interventions in India. These guidelines are tailored to the distinctive philosophies, diagnostic approaches, and treatment modalities of Unani medicine, while aligning with internationally recognized norms of research ethics and regulatory expectations.

Foundations and Objectives

- The Department of AYUSH framed these guidelines in reference to the CDSCO GCP Guidelines (2001) for pharmaceutical trials, adapting them to the unique features of Unani, Siddha, and Ayurveda research.
- Their objective is to ensure trials are scientifically sound, ethically justified, and generate reliable data, all while safeguarding participant rights, safety, and well-being.
- They are mandatory for all clinical trials, at every drug development phase, intended for the licensing or evaluation of Unani medicines in India.

Scope

- Applies to all clinical evaluations of Unani drugs, procedures, or therapies.
- Relevant for both classical (textually described) and proprietary/ patented formulations.
- Encompasses study design, ethical approvals, consent, data handling, reporting, and publication.

Core Principles

1. Ethical Conduct

- Trials must be conducted per the Declaration of Helsinki and should prioritize participant rights, dignity, and welfare above all.
- Research activities require prior approval from an Institutional Ethics Committee (IEC), which oversees ethical integrity at all stages.

2. Scientific Rigor and Transparency

- Trials should be designed with robust scientific methodology (randomization, blinding, appropriate controls where possible) compatible with Unani concepts.
- Protocols must clearly specify objectives, rationale, methodologies, outcome measures, and statistical analysis plans.
- Registration with the Clinical Trial Registry of India (CTRI) is mandatory for transparency.

3. Participant Protection and Informed Consent

- Freely given, informed consent is required from every participant, delivered in clear, local language with standardized information sheets.
- Vulnerable populations must receive special protections, and all risks, benefits, and alternatives must be explained.

4. Safety and Data Integrity

- Continuous safety monitoring is essential, with reporting and management protocols for adverse events.
- All trial data must be recorded, stored, and handled to ensure accuracy, confidentiality, and verifiability for regulatory and ethical review.

5. Roles and Responsibilities

- Each trial requires a qualified investigator (preferably with expertise in Unani and GCP training).
- Sponsors are responsible for oversight, resource allocation, and reporting obligations.

6. Respect for Unani Principles

- Clinical evaluation should honor Unani concepts of diagnosis, patient assessment, drug selection, Mizaj (temperament), and individualized therapy.
- Both classical and novel indications must be scientifically evaluated without compromising on Unani fundamentals.

7. Adherence to National and International Regulations

- Ensures harmonization with global best practices when relevant, while reflecting Indian regulatory and ethical requirements.
- Compliance with Drugs and Cosmetics Rules (including Rule 158B), especially regarding proprietary product licensing, is emphasized.

Key Components of GCP-Unani Trial Process

Element	Details
Protocol Development	Detailed, prespecified, and ethically cleared, explaining Unani rationale and methods
Ethics Approval	Mandatory IEC approval; periodic review of ongoing studies
Informed Consent	Comprehensive, culturally and linguistically accessible; renewed as trial progresses
Safety Monitoring	Regular recording/reporting of adverse events, interim analyses for participant protection
Data Management	Regular recording/reporting of adverse events, interim analyses for participant protection
Publication	Full disclosure of results (positive or negative), maintaining transparency and confidentiality
Stakeholder Involvement	Input from practitioners, patients, regulators, and scientific community aids rigor and relevance

Flexibility and Innovation

- The guidelines encourage adaptability to accommodate technological advancements (such as digital documentation or telemedicine follow-ups) and the increasingly participatory model of clinical research, ensuring relevance and efficiency.
- They support innovative trial designs (e.g., pragmatic trials, adaptive/blended methodologies) when aligned with Unani medical logic.

The GCP-Unani guidelines integrate ethical values, scientific discipline, Unani traditional concepts, and legal requirements to enable meaningful, socially responsible, and evidence-based research. They are designed for both quality assurance and cultural congruence, ensuring

that clinical findings in Unani medicine withstand regulatory, ethical, and scientific scrutiny.

Demonstration of ethical principles through case scenario

A case scenario is presented in the following that demonstrates the ethical principles in biomedical research involving human participants, as outlined by ICMR and international GCP guidelines:

Case Scenario: A Clinical Trial on a New Unani Herbal Formulation for Type 2 Diabetes

Background:

Dr. Amina, a Unani researcher, proposes a clinical trial to test the effectiveness of a new herbal formulation based on Unani principles for managing blood sugar in patients with Type 2 diabetes. The formulation combines ingredients mentioned in classical texts, but the specific composition is novel and requires clinical validation.

The trial is to be conducted at a government medical college with a Unani research wing and is sponsored by a licensed Ayurvedic and Unani pharmaceutical company.

Application of Ethical Principles

1. Respect for Persons (Autonomy)
    - All participants are informed thoroughly about the nature of the study, treatments involved, potential risks, and their right to withdraw at any time without affecting their medical care.
    - Written informed consent is obtained in the local language, and additional consent is taken for storage of biological samples for future research.

2. Beneficence
    - The research is expected to benefit society by offering a potentially effective and affordable alternative to conventional diabetes treatments.
    - Participants benefit from regular health checkups, free medicines, and dietary counseling during the trial.

3. Non-Maleficence
- A prior safety evaluation (animal study and Phase I human trial) indicates no serious side effects.
- Adverse Events (AEs) and Serious Adverse Events (SAEs) will be monitored, documented, and managed with proper medical support.

4. Justice
- Participants are selected fairly from various socio-economic groups, ensuring no exploitation of vulnerable populations.
- No inducements are offered beyond expense reimbursement.

5. Essentiality
- The study is conducted because there is a lack of rigorous clinical data on the specific formulation, despite its common use.

6. Privacy and Confidentiality
- Personal data and medical histories of all participants are kept confidential.
- Coding methods are used so that analysis is done without revealing identities.

7. Community Engagement and Social Responsibility
- Before initiating the study, the research team holds community meetings with local health workers and explains the study's intentions and benefits.
- The results, once available, will be shared with the community and published transparently.

Conclusion

Dr. Amina's trial reflects 'ethical research practice' by ensuring informed consent, protecting participants from harm, promoting equality, and generating trustworthy scientific data—all while respecting the philosophy of Unani medicine. This holistic approach demonstrates how ethical principles can be applied effectively in real-world clinical research.

CPCSEA guidelines

The Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines establish the regulatory framework for animal experimentation in India under the Prevention of Cruelty to Animals Act, 1960. These guidelines aim to ensure the humane treatment of animals used in biomedical and behavioral research.

Core Objectives and Legal Framework

The CPCSEA functions as a statutory body with the fundamental mission of preventing unnecessary pain or suffering to animals before, during, and after experiments. The guidelines operate under the Prevention of Cruelty to Animals Act 1960 (as amended in 1982) and are enforced through the "Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998" with amendments in 2001 and 2006.

Key Principles

The guidelines emphasize several core principles:

- Experiments must be performed by qualified individuals with degrees in Veterinary Science, Medicine, or Laboratory Animal Science
- Proper anesthesia must be used for painful procedures
- Animals sustaining severe injuries during experiments should be humanely euthanized
- Alternatives to animal experimentation should be used whenever possible

Institutional Implementation

Every research facility must:

- Register with the CPCSEA
- Constitute an Institutional Animal Ethics Committee (IAEC)
- Have their animal housing facilities inspected and approved
- Obtain proper clearance for research projects

Since the 2006 amendment, IAECs have been empowered to approve experiments on small animals, while proposals for large animal experiments still require CPCSEA approval.

The 3R Principles

The CPCSEA actively promotes the internationally recognized 3R principles:

- Replacement: Using alternatives to animals when possible
- Reduction: Minimizing the number of animals used
- Refinement: Modifying procedures to minimize pain and distress

Achievements and Impact

The CPCSEA has made significant contributions to animal welfare in research:

- Registration of over 665 laboratories across India
- Formation of IAECs in every registered laboratory
- Development and enforcement of comprehensive laboratory animal care guidelines
- Rehabilitation of hundreds of research animals including dogs, equines, non-human primates, and other species
- Proactive training of scientific and non-scientific personnel on animal welfare issues
- Legal advocacy resulting in verdicts favoring alternatives and animal welfare

The guidelines cover specific protocols for different animal species, including recent additions such as guidelines for poultry/bird facilities (2020), reuse and rehabilitation of large animals (2020), and experimentation on fishes (2021).

Through its comprehensive approach, the CPCSEA has established a robust system for ensuring ethical animal use in research while promoting the development and adoption of alternative methods that reduce animal suffering.

Institutional Human Ethics Committee (IHEC/IEC):

1. Constitution

An Institutional Human Ethics Committee (IHEC/IEC) is formally constituted by the head of an institution (such as a hospital, university, or research center) to review and oversee biomedical and health research proposals involving human participants. The establishment, hierarchical position, and authority under which it operates must be clearly defined by the institution.

2. Composition

The IHEC/IEC is designed to be multidisciplinary and multi-sectoral for comprehensive and balanced review. According to ICMR guidelines and CDSCO requirements, the committee should have at least 7 to 15 members, including:

- Chairperson (Non-affiliated, i.e., from outside the institution; must be respected and experienced, with prior service on an ethics committee)
- Member Secretary (Affiliated, i.e., staff of the institution, with clinical research and ethics experience)
- Basic Medical Scientist(s)
- Clinician(s)
- Legal Expert(s)
- Social Scientist/Philosopher/Ethicist/Theologian
- Lay Person(s) (Non-affiliated, community representative, aware of local language and values)

A minimum quorum of five members with varied backgrounds (medical, non-medical, scientific, and non-scientific) is required for any decision-making. Additional members (like co-chairpersons or additional secretaries) may be included as justified.

3. Review Process

The IEC/IHEC review process is as follows:

- Submission : Investigators submit detailed research proposals, including protocols, informed consent documents, recruitment materials, and relevant appendices.
- Initial Scrutiny: The Member Secretary checks the completeness of submissions.
- Scientific and Ethical Review: Members independently examine proposals for:

- Scientific validity
- Risk–benefit ratio
- Participant selection fairness
- Informed consent adequacy
- Confidentiality measures

- Full Committee Discussion: Proposals are discussed in scheduled meetings. The presence of a quorum is mandatory.
- Decision and Communication: Decisions (approval, modifications, or rejection) are documented and communicated in writing. Reasons for rejection/modification are provided.
- Ongoing Oversight: The IHEC monitors ongoing research through progress reports, adverse event reports, and site visits if required.

4. Registration

Registration with the Central Drugs Standard Control Organization (CDSCO) is mandatory for any IEC/IHEC that wishes to review and approve clinical trial protocols in India:

- Application: Institutions submit applications as per Appendix VIII of Schedule Y, with supporting documents.
- Evaluation: The Licensing Authority assesses compliance with all requirements and may grant registration subject to specified conditions.
- Validity: Registration is valid for 3 years. Institutions must apply for re-registration at least 3 months before expiry. Registration continues unless otherwise stated, or if suspended/cancelled by CDSCO.
- Online Registration: CDSCO encourages submission via the SUGAM online platform for faster processing.

5. Regulation

Each registered IEC/IHEC is:

- Governed by National Ethical Guidelines (ICMR 2017) for biomedical and health research.
- Subject to inspection and monitoring by CDSCO and institutional authorities.
- Required to maintain confidentiality, manage conflict of interest declarations, and adhere strictly to SOPs (Standard Operating Procedures).

- Members must frequently undergo training in ethics and stay updated with regulatory/ethical advancements. Noncompliance may lead to suspension, and all actions are subject to legal and regulatory oversight.

Summary Table: Core Aspects of IEC/IHEC

Aspect	Description
Constitution	Formed by institution head, with authority and structure specified
Composition	7–15 multidisciplinary members (Chairperson, medical scientists, legal, lay, etc.)
Review Process	Submission, scrutiny, review meetings, decision-making, ongoing oversight
Registration	Mandatory with CDSCO; valid for 3 years, subject to renewal
Regulation	National guidelines, monitoring, SOPs, confidentiality, conflict of interest checks

This structure ensures transparent, ethical, and scientifically sound oversight of human research.

Institutional Animal Ethics Committee (IAEC):

Constitution

The Institutional Animal Ethics Committee (IAEC) is formally established under the Committee for the Purpose of Control and Supervision of Experiments on Animals (CPCSEA) guidelines in India, as mandated by the Prevention of Cruelty to Animals Act, 1960. Every research facility that conducts animal experimentation must constitute an IAEC. The committee is constituted by the CPCSEA at the time of registration and is valid for a period of 5 years, after which it must be reconstituted with at least half of the members being replaced to ensure periodic renewal and compliance.

Composition

The IAEC comprises eight mandatory members:

Members from the Institution:

1. Chairperson - Preferably the Head of the Institution/Department, nominated from among the institutional members
2. Biological Scientist
3. Two Scientists from different biological disciplines
4. Veterinarian involved in the care of animals (mandatory for judging level of care and handling)
5. Scientist in charge of the animal facility

CPCSEA Nominees:

1. Main Nominee
2. Link Nominee (substitutes for the main nominee when unavailable)
3. Scientist from outside the Institute
4. Socially Aware Nominee (non-scientific member)

For special projects involving hazardous agents such as radioactive substances or deadly microorganisms, specialists may be co-opted as additional members.

The minimum qualifications for IAEC members include:

- B.V.Sc., or
- M.Sc. in Zoology/Animal Sciences/Animal Biotechnology, or

-M.Sc./M.Tech in Life Sciences/Biological Sciences/Biochemistry/Biotechnology with experience in animal handling, or
- M.Pharm with experience in animal handling, or
- MD/MS with research experience in laboratory animal handling

Review Process

The IAEC review process includes:

1. Reviewing all animal research proposals to ensure they meet ethical standards
2. Monitoring approved studies to prevent unnecessary animal suffering
3. Ensuring compliance with applicable laws and guidelines

The IAEC has different levels of approval authority:

- It can directly approve experiments on animals up to the phylogenetic level of rodents (e.g., mice, rats, and rabbits)
- For experiments on animals higher on the phylogenetic scale than rodents, the IAEC reviews the proposals and forwards its recommendations to CPCSEA for consideration

IAEC meetings are held quarterly, and decisions are made by consensus or majority vote.

Registration

For an institution to establish an IAEC:

1. The institution must first register with CPCSEA
2. The IAEC is constituted at the time of registration
3. Registration must be renewed periodically
4. The committee must follow procedures specified by CPCSEA

Regulation

The IAEC operates under several regulatory frameworks:

1. Legal Framework: Prevention of Cruelty to Animals Act, 1960 and the Breeding of and Experiments on Animals (Control and Supervision) Rules, 1998 (with amendments in subsequent years)

2. Oversight: The CPCSEA has the power to suspend or revoke registration if an institution fails to comply with the guidelines

3. Responsibilities:

- Ensuring compliance with all regulatory requirements, applicable rules, guidelines, and laws
- Preventing infliction of unnecessary pain or suffering on animals
- Taking reasonable measures to ensure the well-being of animals used in research

4. Ethical Standards:

The IAEC must ensure that researchers follow the principles of animal welfare, which include taking all reasonable measures to ensure the well-being of animals and preventing unnecessary pain or suffering[2]

The comprehensive structure of the IAEC, with its multidisciplinary composition and regulatory oversight, ensures ethical conduct in animal experimentation while promoting the principles of animal welfare in scientific research.

Ethical issues specific to Unani medicine research through different case scenarios:

Ethical issues specific to Unani medicine research arise from its unique historical context, philosophical underpinnings, integration with modern approaches, and regulatory environment. Below are illustrative case scenarios addressing such challenges, highlighting relevant ethical concerns:

1. Case: Informed Consent in Herbal Formulation Studies

Scenario:

A researcher conducts a clinical trial of a 'classical Unani polyherbal formulation for skin disorders'. Most participants are from rural backgrounds, with limited formal education.

Ethical Issues:

- Comprehension: Participants may not fully understand research procedures or the distinction between traditional care and research interventions, risking inadequate informed consent.
- Integration of Traditional Knowledge: Consent forms require careful tailoring to clarify that the intervention, though traditional, is being tested under research conditions—not routine care.
- Voluntariness: Potential perception of authority or therapeutic misconception among patients towards Unani practitioners may compromise voluntariness.

2. Case: Use of Non-Codified or Proprietary Formulations

Scenario:

A company sponsors research on a 'new proprietary Unani formulation' not described in classical texts.

Ethical Issues:

- Safety & Efficacy Evidence: Unlike codified drugs, proprietary products require full preclinical and clinical safety data before human studies, as per regulatory guidelines.
- Misleading Claims: Marketing of such products as "Unani" without adequate evidence amounts to ethical misconduct.

- Transparency: Participants and ethics committees must clearly understand the novel nature and regulatory status of the product.

3. Case: Cultural Sensitivity and Community Engagement

Scenario:

A Unani clinical study is proposed among a minority population where traditional beliefs may affect research participation.

Ethical Issues:

- Respect for Beliefs: Ensuring the research design and consent process respects community values and traditional knowledge.
- Community Engagement: Ongoing engagement is required to build trust, prevent exploitation, and address cultural sensitivities.

4. Case: Confidentiality and Use of Traditional Knowledge

Scenario:

Researchers collect detailed histories involving family remedies and traditional healing secrets as part of an ethnopharmacological study.

Ethical Issues:

- Confidentiality: Safeguarding personal health information and community knowledge from misuse or unauthorized publication.
- Benefit-Sharing: Obligations for fair benefit-sharing and recognition when commercial products result from community-sourced knowledge.

5. Case: Integrative Trials with Modern Medicine

Scenario:

A hospital runs an integrative clinical trial combining Unani therapy and modern drugs for lifestyle disorders.

Ethical Issues:

- Ethics Committee Expertise: Ensuring inclusion of Unani subject experts in the ethics review process and preventing conflicts of interest, as required by ICMR guidance.

- Risk of Drug Interactions: Addressing data gaps on herbal-drug interactions and monitoring for unexpected adverse events.
- Clarity for Participants: Clearly communicating the roles and expected effects of each intervention to participants.

6. Case: Exploitation of Vulnerable Populations

Scenario:

A free Unani medical camp collects clinical data for research from economically disadvantaged participants.

Ethical Issues:

- Non-Exploitation: Safeguards must be in place to ensure vulnerable groups are not targeted merely for easy recruitment and that participation is truly voluntary, with fair compensation if appropriate.
- Benefit and Burden Distribution: Outcomes of research must benefit the community involved, and burdens should not fall disproportionately on them.

Summary:

These cases highlight central ethical challenges in Unani medicine research, including 'informed consent', 'safety and regulatory oversight for non-codified products', 'community engagement', 'privacy','fair benefit-sharing', and 'avoidance of exploitation'. National guidelines require rigorous adherence to general bioethical principles—autonomy, beneficence, non-maleficence, and justice—while also accounting for the distinct features of Unani practice and cultural contexts

Publication ethics

Publication ethics refers to a set of principles and standards that guide the responsible conduct of publishing scientific research, ensuring integrity, transparency, and respect for both participants and the academic record. In Unani medicine and its related sciences, adherence to publication ethics is essential for scientific credibility, protection of research participants, and alignment with both classical values and modern best practices.

Key Elements of Publication Ethics:

Authorship and Originality:

Authors must ensure that manuscripts are their own original work, not published elsewhere, and not under consideration by another journal. All contributors should meet standardized criteria (as per ICMJE), including significant contribution, drafting or revising content, approval of the version to be published, and accountability for the work. Gifted or ghost authorship is unethical, and authorship disputes must be resolved by the institution.

Transparency and Honesty:

Data, findings, and methods must be reported honestly and transparently, avoiding fabrication, falsification, or selective reporting of results. All data should be authentic and verifiable, and errors or inaccuracies must be corrected promptly via errata or retractions as needed.

Ethical Approval and Informed Consent:

For studies involving human participants, approval by an independent ethics committee is mandatory, and informed consent from participants must be documented. Research with animals must conform to national and international ethical guidelines, and relevant permissions should be obtained.

Conflict of Interest Disclosure:

Authors must declare any potential financial or personal conflicts of interest that could bias the work. Even if none exist, an explicit statement is required.

Peer Review Integrity:

Peer reviewers must treat manuscripts as confidential, review objectively, identify relevant uncited work, and declare their own conflicts of interest. They should provide clear, evidence-based feedback and not misuse unpublished data.

Editorial Responsibilities:

Editors hold full authority to accept or reject articles and are responsible for maintaining the quality and ethical standards of the publication. Editorial decisions must be based on the importance, originality, and clarity of the submission, not personal bias. Editors should act upon suspected misconduct and correct the academic record where necessary. Reviewer anonymity and disclosure of funding sources should be assured.

Plagiarism and Redundant Publication:

Plagiarism (copying others' work without proper citation) and redundant publication (publishing the same findings multiple times) are unacceptable and lead to rejection or retraction.

Protection of Subjects:

Research must minimize potential harm, maximize benefits, protect privacy, and comply with local and international legal and ethical norms, such as the Declaration of Helsinki. For human studies, researchers must ensure confidentiality and the right to withdraw.

Post-Publication Responsibilities:

If errors, ethical issues, or new conflicts arise after publication, authors and editors are obliged to address, correct, or retract the publication as appropriate.

Specific Guidelines Relevant for Unani Medicine Journals:

- Journals like the Hippocratic Journal of Unani Medicine require explicit statements on conflict of interest, ethical approval, and informed consent at submission.
- Indian Council of Medical Research (ICMR) and international guidelines (e.g., Declaration of Helsinki, Belmont Report) provide frameworks that must be followed for research involving human subjects.

- Case reports, case series, and other research from Unani practice must meet all publication and ethical standards to be accepted and recognized internationally.

Caveats and Challenges:

- Adherence to both classical Unani values and modern ethical requirements can sometimes create dilemmas, so ethical vigilance and continuing education are essential for researchers and editors.
- Journals may have slight variations in ethical requirements; authors must check specific journal policies in advance.

Publication ethics in Unani medicine thus involves a rigorous, transparent, and fair approach to research and its communication—upholding both scientific integrity and the traditional values of Unani healthcare.

Chapter 6.
Research process

Process for selection of topic

The process of selecting a research topic in Unani medicine involves several systematic steps to ensure the topic is relevant, evidence-based, and contributes to the advancement of the field. The topic selection in Unani medicine research is a structured, collaborative, and evidence-based process that integrates critical appraisal of classical knowledge with modern scientific methodology to address relevant healthcare issues and advance the field. The key stages are:

1. Literature Review: Researchers begin by conducting a thorough literature search, critically analyzing both classical Unani texts and contemporary scientific studies. This helps identify gaps in existing knowledge and areas where Unani principles can be further explored or validated.

2. Identification of Research Problem: After reviewing the literature, researchers identify a specific research problem or area of interest. This involves understanding health issues, traditional treatments, and the scope for scientific exploration within the Unani context. The topic should address either a current health need or aim to validate/classify a traditional concept.

3. Formulation of Research Question and Hypothesis: The next step involves refining the identified problem into a clear research question and formulating a testable hypothesis. Frameworks such as PICOT (Population, Intervention, Comparison, Outcome, Time) and FINER (Feasible, Interesting, Novel, Ethical, Relevant) are commonly used for this purpose in Unani research training.

4. Consultation and Expert Input: Input from subject experts, practitioners, and mentors is often sought to ensure the research topic's feasibility, ethicality, and alignment with priority areas in Unani medicine.

5. Selection Based on Relevance and Feasibility: The identified topics are evaluated for practical feasibility, ethical considerations, and significance to healthcare. Preference is given to projects likely to fill knowledge gaps, improve patient care, or document/classify traditional remedies with scientific rigor.

6. Assessment of Evidence and Resources: The level of existing evidence is reviewed; topics lacking sufficient documentation or requiring new evidence are prioritized. Availability of resources (case studies, patients, materials) and institutional capabilities are considered.

7. Finalization and Protocol Development: The selected topic is formulated into a detailed research protocol, outlining objectives, methodology, anticipated challenges, and ethical safeguards. This protocol is then submitted for institutional and ethical review before commencement.

Experiential learning activities further enhance the process, with students often participating in group discussions to identify real-world research gaps, frame research questions, and propose solutions based on both traditional and modern perspectives.

Literature search in a medical database

A literature search in a medical database is a systematic process for identifying and retrieving scholarly information relevant to a clinical or research question. The main steps include:

Formulate a focused research question: Clearly define the problem or topic to guide your search. Frameworks like PICO (Population, Intervention, Comparison, Outcome) help construct answerable questions.

Identify key concepts and synonyms: Break down your question into main concepts and consider alternative terms, including medical subject headings like MeSH (Medical Subject Headings) in PubMed. This improves search effectiveness by covering synonyms and related terms.

Choose the right database: Select appropriate databases for your topic (e.g., PubMed, Embase, Cochrane Library). Each database has strengths and may use different indexing terms.

Develop a search strategy: Combine keywords and subject headings using Boolean operators (AND, OR, NOT). Use parentheses for grouping terms and apply search field tags as needed (e.g., [tiab] for title/abstract in PubMed).

Apply limits and filters: Refine results by date, publication type, language, population, age group, etc., to narrow the search to the most relevant literature.

Review and revise: Evaluate the retrieved articles for relevance. Adjust your search terms, operators, or filters as needed for completeness and accuracy. Searching is often iterative.

Document the search: Record your search strategies, databases used, and filters applied for transparency and reproducibility.

This process helps ensure a comprehensive, unbiased retrieval of the current medical knowledge related to your research question.

Systematic Literature Review

A systematic literature review (SLR) is a rigorous and structured method to identify, evaluate, and synthesize all relevant research studies on a precise research question. It aims to provide a comprehensive, unbiased summary of existing evidence and identify research gaps. The detailed steps of conducting a systematic literature review are as follows:

1. Develop a Protocol and Register the Review

- Define a clear research question using frameworks such as PICOS (Population, Intervention, Comparator, Outcomes, Study design).
- Write a detailed protocol describing the review's background, objectives, inclusion/exclusion criteria, data extraction methods, and analysis plan.
- Register the protocol in a public database such as PROSPERO to ensure transparency and avoid duplication.

2. Comprehensive Literature Search

- Perform an exhaustive search across multiple electronic databases relevant to the topic (e.g., PubMed, Embase, Cochrane Library).
- Use a well-crafted search strategy combining keywords, synonyms, and controlled vocabulary (like MeSH terms) with Boolean operators (AND, OR, NOT).
- Apply predefined limits like publication dates, language, or study type, but avoid unnecessary restrictions to maximize comprehensiveness.

3. Screening of Studies

- Conduct an initial screening by reviewing titles and abstracts to exclude clearly irrelevant studies.
- Follow this with a full-text screening of the remaining studies to assess eligibility according to inclusion and exclusion criteria.
- This screening should be done independently by at least two reviewers to minimize bias, with disagreements resolved by discussion or a third reviewer.

4. Data Extraction and Quality Assessment

- Extract relevant data systematically from included studies into a data extraction table, capturing details like study design, participants, interventions, outcomes, and results.

- Simultaneously, assess the methodological quality and risk of bias of each study using standardized tools appropriate for the study design (e.g., Cochrane Risk of Bias tool, Newcastle-Ottawa scale).
- This assessment informs the interpretation of results and decisions about including studies in quantitative synthesis.

5. Data Synthesis

- Summarize findings qualitatively and, where possible, quantitatively through meta-analysis, which pools data to estimate overall effects.
- Assess heterogeneity (variability) among study results and explore sources through subgroup analyses or sensitivity analyses.
- If meta-analysis is not feasible, narrative synthesis highlighting key patterns and differences is performed.

6. Reporting and Interpretation

- Write a comprehensive report detailing the methodology, search flow (often shown with a PRISMA flow diagram), results, quality assessment, and synthesis.
- Discuss how findings answer the research question, the strength and limitations of evidence, potential biases, and implications for practice and future research.
- Follow reporting guidelines such as PRISMA for clarity and transparency.

7. Optional - Hand Searching and Reference Checking

- Supplement database searches with manual searches of conference proceedings, gray literature, and reference lists of included studies to find additional relevant work.

This process ensures transparency, reproducibility, and minimizes bias, providing a high level of evidence useful for healthcare decision-making and guiding future research directions.

Sources in Literary Research

The process of literary research requires the researcher to utilize the libraries in the best possible ways without wasting much time. The ability to do so is only acquired by experience and continuous efforts in a systematic way. The first possible step in literary research is to gather the primary sources (all the works by the author you are studying) and then collect the secondary sources(all the works written about the author you are studying). One of the easiest methods of tracing the sources is by referring the bibliographies and library catalogues.

Primary sources:

These are the first or the original work done in the subject under discussion. These include both published and unpublished (grey literature) material. Examples: dissertations, journals, conference proceedings, manuscripts, government publications, reports, etc.

Dissertation or thesis: It is a long essay written on a specific subject for partial completion of a university degree. Dissertations are usually prepared during Ph.D, M.Phil, M.D. by research scholars. Although dissertations are a good source of detailed information but they are difficult to locate and if located they cannot be easily accessed because there is usually only one copy of a thesis at the awarding institution. The Central Council for research in unani medicine (CCRUM) has successfully developed a database of MD thesis awarded at CCRUM and is developing a dissertation database of academic research done in various subjects at different institutes in India. A Post-graduate thesis compendium of academic research in Moalejat department of Ajmal Khan Tibbia College, Aligarh was also published by CCRUM.

Journal: It is a newspaper or magazine which is published regularly on a particular subject or about activity of a profession. Also called serials or periodicals journals are important source of information. They can be easily accessed from institutional or university libraries either in print form or electronic form through the services of libraries. Some of the journals publishing research regarding unani system of medicine are as follows:

Sl.No	Name of the journal	Name of the Publisher	Period of publishing

1.	Hippocratic Journal of Unani Medicine	CCRUM, New Delhi	Quarterly
2.	Indian Journal of Unani Medicine	National Environmental Science Academy (NESA)	Yearly
3.	Indian Journal of Traditional Knowledge	NISCAIR, Delhi	Quarterly
4.	Jahan-e-Tibb	CCRUM, New Delhi	Quarterly
5.	Journal of Research in Unani Medicine	NIUM, Bangalore	Bi-annual
6.	Tarjuman e-Tib	NIUM, Bangalore	Bi-annual

There are a lot of journals publishing information on traditional system of medicine (AYUSH) such as AYUSHDHARA, International Journal of Advanced Ayurveda, Yoga, Unani, Siddha and Homeopathy, The Journal of Ayurveda and Integrative Medicine (J-AIM), Journal of Ayurveda and Integrated Medical Sciences, The Journal of Research & education in Indian Medicine, Journal of AYUSH, International Journal of AYUSH, International Journal of Herbal Medicine, etc.

Some of the journals published by private organizations or individuals include Ahmed times, Al-Shifa, Barkat-e-Tibb, Hakeem Haziq, Hamdard sehat, Mahnama Fikro Sehat, Mahnama Hamdard, Masail Deen Dunya aur Tibb, Niamath's Herbal Unani Medicine, etc

Compendium: It is a short but detailed collection of information on a particular subject in the form of a book.

Manuscript: This may refer to a handwritten or typed copy of a book which is not yet published (or) an old document which is written by hand rather than being typed.

Government publications: These could include reports, reviews, legislative acts or any other documents published by the government.

Report: This is a description about an investigation or an observation to someone. A report may be written by an individual researcher or an organization. The CCRUM publishes two types of reports i.e. technical report and annual reports.

Secondary sources:

These are the sources that interpret, explain or refer to primary sources. Often scholars in sub-disciplines study and present the specific aspects of primary sources. Examples: monographs, reviews, meta-analysis of a subject, etc.

Monograph: This is detailed written information on a single specialization of a subject. This could be a long article or a short book.

Review: This is a formal evaluation or assessment of a publication or service by an expert.

Meta-analysis: This is a type of research method in which result many researches are combined to produce better results or to determine overall trends.

Tertiary sources:

These are collection of information from both primary and secondary sources and they provide an introduction to a topic. They are also called as search tools because they help in locating primary and secondary literature. Examples: indices, catalogues, bibliographies, encyclopedias, directories, etc.

Index: This is an alphabetical list of collection of books or list of authors, titles maintained in a library.

Catalogue: It is a systematic record of all the bibliographic items available in the library either physically or electronically. The catalog includes all the books, e-books, DVDs, CDs, thesis, musical scores, audio recordings and all the other items that the library owns or for which it offers electronic access. Library catalogues are available online as well like COPAC (http://copac.ac.uk) and WorldCat,etc. WorldCat is the world's largest bibliographic database.

Bibliography: This is a list of all the books or articles and other kinds of sources referred in the preparation of the project. It is usually mentioned at the end of the book.

Encyclopedia: This is a book or a set of books containing information on various subjects or various aspects of a particular subject.

Newspapers: Electronic and printed sources: Newspapers provide an important source of book and performance reviews, publisher's advertising, serialization, editorial comments and interviews of the author. The Times Digital Archive 1785-1985 is one of the most important newspaper collections available on the internet.

Medical News Index:
In 1980, the library and information centre at CCRUM launched a monthly news publishing service called "Medical News Index". The library and information centre puts effort to collect news originally published in different national dailies and creates their abstracts before indexing them subjectwise and alphabetically. The aim is to disseminate information among the research scholars and medical fraternity.

Using the Computer:
The use of computer enables a simple and efficient way of finding a particular topic by its title, or a particular author by its name. Intelligent and experienced computer users often make the search with the keywords that are most likely to lead to the relevant topics. A researcher needs to acquire skill of using the available online indexes and find the abstracts of books and journal articles which will help in understanding the scope of the related subject of study.

Search engines: Different search engines such as PubMed, Web of science, BIOSIS and Google scholar can be used for searching biomedical literature. PubMed provides access to 27 million literature citation of biomedical sciences from databases such as MEDLINE, Index medicus, PMC citations, etc. Google scholar is another useful search engine providing results from various materials such as books, theses, abstracts, articles, etc Google scholar is not considered as the most trustworthy by some of the experts because of lack of control of specificity and accessibility. Nevertheless it also provides an access to some of the basic information related to different sciences. Some other useful databases include The Cochrane Library (http://www.thecochranelibrary.com), Health Business Elite, CINAHL, Psychology and behavioural sciences collection, SIGLE (System for Information on Grey Literature in Europe) (http://www.opengrey.eu/), Lenus (http://www.lenus.ie/), Rian (http://rian.ie/), SCOPUS, Embase, etc.

United States National Library of Medicine: This is the world's largest biomedical library having a vast collection of books, manuscripts, journals, technical reports, photographs microfilms in print and electronic forms.

Google Books: Google Inc. provides a library service called Google Books which allows a user to search and read books and magazines that were scanned by Google through Optical Character Recognition (OCR). The books can be searched by entering their title, author, ISBN and keyword while the magazines can be searched by their title, ISSN. There are over 25 million books in the Google Books (as on October 2015) that are provided with four different access levels namely full review, preview, snippet view and no preview.

Research Problem

The first step after selecting research topic is to state the research problem in clear terms. Stating the research problem removes ambiguities (if any) and provides a sharper focus to the topic. In fact, some authors regard the research problem as an integral part of selecting research topic as it provides the base for construction of the research objective, the hypothesis and the research methodology.

A good research problem describes the relationship between two or more variables in the form of a question and is capable of being tested through data derived from the investigation or the experimentation. Example of research problem: (1) Will sufoof e muhazzil be effective in lowering the cholesterol levels in patients with hypercholesterolemia? (2) Can majoon e falasefa help in minimizing geriatric complications?

By stating the research problem an investigator can understand what kind of data is to be collected during the research i.e., it explains the details of relevant data collection and separates it from irrelevant data. The research problem helps the researcher in describing the problem systematically and emphasizing its importance and priority in the population under study.

Sources of the research problem:

The selection of research problem often becomes a difficult task because to meet the criteria of selection requires serious responsibility, commitment, intellect and experience. It is wise to know the sources of research problem and use them skillfully.

(a) *Research problem from expert:* Generally, in academic research the guide who is an expert in the subject provides the problem in general terms and the researcher shapes it and gives it a sharper focus.

(b) *Research problem from folklore:* proverbs, sayings, beliefs provide help in framing the research problem serving as a source of knowledge. They need to be verified by applying the knowledge of science and technology.

(c) *Research problem from insight:* sometimes gut feelings, intuition may be able to help the researcher in deciding the research problem. It is risky to trust only the gut feelings but the fact that it interests the researcher helps in proceeding with the research problem.

(d) *Research problem from informal discussion:* A group of friends might start an informal discussion which turns out to be an interesting source

of research problem for the friend in the group who is a researcher. He applies his knowledge in searching more answers regarding the subject of discussion.

(e) *Research problem from extracurricular activities:* A special skill or activity outside the field of study possessed by a researcher helps in selecting research problem. It is realized that the knowledge of other apparatus can be applied in the research project with success since the researcher already possesses an extra skill.

(f) Research problem from reading literature: While studying literature certain doubts arise which often remain unanswered. Upon further reading or referring other books it is realized that the doubts could serve as potential sources of the research problem.

Hypothesis

A hypothesis is a clear, specific, and testable statement that predicts a relationship between two or more variables. It is essentially a tentative explanation or prediction about an observable phenomenon based on existing knowledge, which can be tested through research or experimentation.

WHO definition “Hypotheses are carefully constructed statements about a phenomenon in the population”.

In research, a hypothesis guides the direction of a study by proposing what the researcher expects to find and allows for empirical testing to confirm or refute it.

In simpler terms, it is an educated guess or explanation that you formulate before conducting your research, which you then test to see if it holds true.For example, a hypothesis might be: "Students who sleep at least 8 hours per night will, on average, achieve higher grades than students who sleep less than 8 hours." This statement is clear about the variables (sleep hours and grades) and the expected relationship (more sleep leads to higher grades).

Thus, a hypothesis is not just any guess but a precise, testable proposition that forms the foundation of scientific inquiry.

Formulation of Hypothesis

In health care research, formulation of hypothesis is used to find the cause of disease and the disease distribution in populations.Mill’s canons of inductive reasoning which explains relation between association and causation is used in the formulation of hypothesis. It is explained as follows:

Method of agreement: Suppose three patients visit a physician, all of them complaining of indigestion. When the physician asks he comes to know that first patient had plain rice and vegetable curry, second patient had chapatti and vegetable curry, third patient had fried rice and vegetable curry. The physician concludes that vegetable curry is responsible for causing indigestion in all of them. The example is an application of methods of agreement which states:

“If two or more instances of the phenomenon under investigation have only one circumstance in common, the circumstance in which alone all the instances agree, is the cause (or effect) of the given phenomenon”— John Stuart Mill.

Method of difference: Suppose two friends visit a physician and the second one complains of indigestion, the first one had rice and curry made from Bengal gram while the second one had rice and vegetable curry. The physician concludes that vegetable curry in this case caused indigestion. This reasoning applied method of difference which is stated as:

"If an instance in which the phenomenon under investigation occurs, and an instance in which it does not occur, have every circumstance save one in common, that one occurring only in the former; the circumstance in which alone the two instances differ, is the effect, or cause, or a necessary part of the cause, of the phenomenon"— John Stuart Mill.

Joint method of agreement and difference: Suppose six friends come to the physician, out of them first three had taken vegetable curry and are complaining of indigestion while the next three had not taken vegetable curry and are healthy. This situation explains joint method of agreement and difference and it is stated as :

"If two or more instances in which the phenomenon occurs have only one circumstance in common, while two or more instances in which it does not occur have nothing in common save the absence of that circumstance; the circumstance in which alone the two sets of instances differ, is the effect, or cause, or a necessary part of the cause, of the phenomenon"— *John Stuart Mill.*

Method of concomitant variations: Suppose the physician examines five friends, the first ate no vegetable curry and is healthy, the second had two teaspoon of vegetable curry and is having moderate epigastric pain, the third one had two tablespoon of vegetable curry and has to be admitted to hospital. This is application of method of concomitant variation which is stated as:

"Whatever phenomenon varies in any manner whenever another phenomenon varies in some particular manner, is either a cause or an effect of that phenomenon, or is connected with it through some fact of causation"— John Stuart Mill.

Method of residue: Suppose a physician during his prior observations found that having a specific brand of tomato ketchup causes itching; now a patient visits him who complains of itching and indigestion. He has taken bread, vegetable curry and tomato ketchup, the physician already knows that having a specific brand of tomato ketchup causes itching so he concludes the additional effect i.e. indigestion is caused by

bread and vegetable curry. This exemplifies method of residue which states:

"Subduct from any phenomenon such part as is known by previous inductions to be the effect of certain antecedents, and the residue of the phenomenon is the effect of the remaining antecedents"—*John Stuart Mill.*

Significance of hypothesis:

- Hypothesis brings clarity and focus to the research problem thus explaining the specific aspects of research problem to be investigated.
- It provides guidelines in the collection of relevant data thereby saving time by not collecting the irrelevant data.
- Hypothesis provides objectivity to the research project.
- Since hypothesis can be tested, it can be used in the formulation of theory.

Types of Hypothesis:

While conducting the research there should be only one hypothesis which is the research hypothesis; however for the purpose of statistical analysis hypothesis is classified as

1. Null Hypothesis
2. Alternative Hypothesis

Null Hypothesis: It is always that hypothesis which states that there is no significant difference between groups or population under study. Suppose there is a disease 'A' and the researcher is interested in knowing its prevalence in two populations 'X' and 'Y'. Then the null hypothesis will be stated as "The prevalence of disease 'A' is same in population 'X' and population 'Y'." The null hypothesis is denoted as $H_{o.}$ Let us suppose prevalence in population X is denoted as P_x and prevalence in population Y is denoted as P_y. Then null hypothesis is symbolically expressed as:H_o **:** $P_x = P_y$

Generally, the null hypothesis doesn't state a specific value. However after statistical analysis the null hypothesis might be rejected or not rejected. It is important to note that the null hypothesis can never be accepted. After analyzing the data statistically the researcher may reject the hypothesis i.e. he may state that there is a difference between two groups or he may not reject the null hypothesis i.e. he

may state that he is not able to detect any difference statistically although there could have been a significant difference in reality.

Alternative Hypothesis: It is always that hypothesis which states that there is a significant difference between groups or population under study. Alternative hypothesis is denoted as H_a. For the example stated above alternative hypothesis will be stated as the prevalence of disease A in population X is not equal to prevalence in population Y. This can be symbolically expressed as:$H_a : P_x \neq P_y$

However, if the prevalence in both populations is not equal then we can have more than one alternative hypothesis. The first alternative hypothesis will state that the prevalence in population X could be less than prevalence in population Y; the second alternative hypothesis will state that the prevalence in population X could be more than the prevalence in population Y. Symbolically denoting this as:

$H_a : P_x < P_y$

$H_a : P_x > P_y$

Steps in Unani Hypothesis Formulation

Unani medicine adheres to the general scientific process of hypothesis formulation but adapts each step to its unique classical framework and principles. Here are the key steps involved:

1. Identify the Research Problem in Unani Context

- Choose a health issue or disorder as interpreted in Unani medicine (e.g., excessive phlegm, imbalance in mizaj) based on clinical observations, classical texts, or recent trends.

2. Literature Review (Unani & Modern Sources)

- Conduct a comprehensive review of classical Unani texts (e.g., Canon of Medicine, Al-Hawi) and contemporary research to understand existing concepts, treatments, and gaps related to the chosen problem.

3. Define Unani Variables

- Specify independent variables (e.g., a Unani drug/formulation, regimen, or intervention) and dependent variables (e.g., changes in mizaj, symptoms, or specific humoral states) within Unani conceptual categories.

4. Theoretical Basis Using Unani Principles

- Clearly relate the intervention's rationale to Unani theory—such as the restoration of humoral balance, correction of temperament, or effect on the six essentials of life (asbab-e-sitta zaruriyya).

5. Draft the Unani Hypothesis Statement

- Formulate a testable and clear hypothesis that predicts the effect of the intervention within the Unani paradigm. The statement must specify expected changes, referencing core Unani concepts (e.g., "administration of X will restore mizaj and balance akhlaat in patients with Y").

6. Empirical Testability

- Ensure the hypothesis can be tested through measurable clinical or laboratory outcomes—this can include Unani clinical assessments (tongue, pulse, mizaj evaluation), and modern biomedical parameters if relevant.

7. Review and Refine

- Refine the hypothesis for clarity, precision, and alignment with Unani doctrine. Seek input from Unani scholars, clinical experts, and research peers for validation.

8. Finalize the Hypothesis

- Finalize a concise, structured hypothesis ready to guide research protocols, ensuring it bridges traditional Unani logic with scientific methodology.

Example

"If daily administration of Majoon Suranjan to patients with waja-ul-mafasil (arthritis) and cold temperament is given for 6 weeks, then there will be significant reduction in joint pain and correction of cold mizaj, supporting Unani theory of restoring equilibrium among humours and temperaments."

Aims & Objectives of Research

The aims of research are broad statements of the overall purpose or goal of your study. They summarize what you intend to investigate or achieve in a concise way. The aim is generally a single sentence that describes the main focus of the research and what you ultimately want to find out.

The objectives of research break down this broad aim into specific, clear, and measurable steps that you will take to achieve the aim. Objectives are focused on smaller, practical tasks or goals that guide your research methodology and data collection, often formulated as specific questions or outcomes you want to address.

How to write aims and objectives:

1. Writing the Aim:

- Make it broad but focused on the central purpose of the study.
- Write a clear, concise sentence that answers “What do I want to achieve?”
- It often starts with verbs like: "To investigate," "To explore," "To assess," or "To determine."
- Example: "To investigate the effect of inpatient counseling on diabetes patient readmission rates."

2. Writing the Objectives:

- Objectives should be specific, measurable, achievable, relevant, and time-bound (SMART).
- Break the aim into practical steps or outcomes.
- Use action verbs like "Review," "Measure," "Compare," "Analyze," "Evaluate."
- Focus on what you will do, how, and sometimes when.
- Usually listed as numbered points.
- Example objectives for the aim above:
  1. Review existing literature on diabetes patient counseling.
  2. Define criteria for patient readmission.
  3. Design counseling intervention.
  4. Collect and analyze patient admission data.
  5. Report findings.

Summary:
- Aim = What is the overall goal of the research? (broad, general)
- Objectives = How will you achieve this aim? (specific, clear, measurable steps)

Well-defined aims and objectives ensure your research stays on track and clarify the scope and direction for readers and researchers alike.

Procedure to conduct research in Unani medicine

The procedure to conduct research in Unani medicine follows a structured scientific approach adapted to Unani principles, including a clear definition of research objectives, literature review, selection of variables, methodology design, and empirical testing with appropriate tools. The materials and methodology section typically includes details of interventions/drugs, study design, sample selection, evaluation criteria, and data analysis methods.

In conducting research in Unani medicine, the Materials and Methodology section is a critical part that details the specific substances, tools, procedures, and research design used to test the hypothesis while integrating Unani concepts with scientific research standards.

Materials in Unani Medicine Research

Unani Formulation or Intervention: Describe in detail the Unani drugs, formulations, or therapeutic regimen used. This includes:

- Botanical, mineral, or animal origin components.
- Preparation methods and standardization procedures to ensure quality, purity, and consistency.
- Dosage form (e.g., powder, decoction, plaster), dose size, frequency, and route of administration.
- Source authentication and quality control measures according to pharmacopoeial standards.

Sample/Participants:

- Criteria for participant selection (e.g., age, gender, specific Unani diagnosis such as temperament or humoral imbalance).
- Inclusion/exclusion criteria explained clearly.
- Sample size estimation and justification.

Equipment and Consumables:

- For clinical assessment: instruments for pulse diagnosis, mizaj evaluation tools if available.
- For biomedical analysis: laboratory instruments and kits for blood tests, biochemical assays, imaging, etc., if combined with modern parameters.

Tools in research

These are the vital materials required to perform the research. They help the researcher in collection of data and construction of various aspects of the research project. There are different tools which should be selected according to the requirement of the research design and availability of the tools. Some of the tools are interviews, questionnaires, scales,etc.

The Interview Method:

According to Monette et al (1986:156), an interview involves an interviewer reading questions to respondent and recording their answers. The researcher decides the content and format of questions to be asked. Interview method allows inclusion of certain respondents groups (illiterates, blind, bed-ridden, etc) who cannot be included in other methods.

Types of Interview:

Unstructured interview: In this type the interviewer takes complete freedom of selecting words in framing questions and asking them in any sequence he wishes or even asks unplanned questions as per the demand of the situation. The aim is to adopt a holistic approach and collect life history of the respondent. The interviewer allows the respondent to talk freely about whatever he thinks is important while the interviewer asks very few questions.

It may be assumed that the unstructured interviews are easiest to conduct but this is not the fact because the interviewer firstly needs to establish a bond of trust with the respondent to make him express freely and secondly the unstructured interviews provide large data which are difficult to analyze.

The unstructured interview is used in both qualitative and quantitative research. Often the interviewer record interviews and writes data as transcripts to analyze it later

Structured Interview: This is like a formal interview or job interview in which the interviewer asks a set of predetermined questions in a standard order. Even the words of the questions are predetermined and framed thoroughly before the interview. This type of interview can be conducted quickly and they can be replicated as well because only fixed

a number of questions are being asked. This method is used in quantitative research and can be performed personally or over the telephone.

Personal Interview: In this, the interviewer asks questions to the respondent face to face. The interview can be structured or unstructured but usually structured method is applied. Personal interview can be direct in which the concerned person is interviewed or it can be indirect in which some other person who is supposed to have the information is cross-examined. Government appointed commissions use the indirect method.

Telephonic Interview: It is mostly used in developed areas wherein the respondents are contacted directly through telephone.

Questionnaire:

It is a list of series of questions (printed or mimeographed) with spaces provided for answers to be filled by or for the respondent. This type of data collection is widely used in clinical, epidemiological and demographic research. From physician to researchers, private individuals to public organizations questionnaire help everyone in collecting the required data.

While conducting big enquiries, a pilot study is advisable to test the validity of the questionnaire before conducting the actual survey. By replicating the questionnaire before the study the feasibility can be tested and any weaknesses in the questionnaire can be brought into notice. Hence overall improvement can be made in the questionnaire.

Types: (i) Questionnaire are often sent by post or e-mail to the respondent who is requested to answer and return the questionnaire. This type requires low cost to conduct but the response rate is usually low.

(ii) Questionnaire can be read out on the telephone to the respondent, but in this method not all the respondents can be reached easily. This method is of little use and can be employed in selective studies.

(iii) Questionnaire are commonly read and completed face to face by trained interviewer in clinical research and community trials. In this, the response rate is high and the interviewer can probe the questions further if needed. Moreover the clarity of answers is increased and within less span of time the questionnaire can be completed.

(iv) Standard questionnaire or inventory is a questionnaire prepared specially to measure an individual's interests, aptitude, traits, etc. A specific method of scoring and analysis is employed in measuring them. It is employed in conduction community surveys; also used in psychology and psychiatry to assess different behavioral phenomenon.

Examples:

a)London School of Hygiene Cardiovascular Questionnaire: It is a performed by trained interviewers who conduct community survey of cardiovascular diseases. The diagnosis can be made from the answers with the help of criteria provided at the end of the questionnaire.

b) California Personality Inventory: This is a true/false self report which is designed to measure personality traits. It is employed in counseling situations and moderate psychopathology.

LONDON SCHOOL OF HYGIENE CARDIOVASCULAR QUESTIONNAIRE (FOR ADMINISTRATION BY AN INTERVIEWER)

Section A: Chest pain on effort

1. Have you ever had any pain or discomfort in your chest?
   ____ Yes
   ____ No
   If 'No', proceed to Section C. If 'Yes', ask next question. (if, during the remainder of Section A, an answer is recorded in a box marked; proceed to Section B.)
2. Do you get it when you walk uphill or hurry?
   ____ Yes
   ____ No
   ____ Never hurries or walks uphill
3. Do you get it when you walk at an ordinary pace on the level?
   ____ Yes
   ____ No
4. What do you do if you get it while walking?
   ____ Stop or slow down
   ____ Carry on
   Record 'stop or slow down' if subject carries on after taking nitroglycerine.
5. If you stand still, what happens to it?
   ____ Relieved
   ____ Not relieved
6. How soon?
   ____ 10 minutes or less
   ____ More than 10 minutes
7. Will you show me where it was?
   ____ Sternum (upper or middle)
   ____ Sternum (lower)
   ____ Left anterior chest
   ____ Left arm
   ____ Other (Record all areas mentioned)
8. Do you feel it anywhere else?
   ____ Yes
   ____ No
   (If 'Yes', record additional information above)

Section B: Possible infarction

9. Have you ever had a severe pain across the front of your chest lasting for half an hour or more?

____ Yes
____ No

Section C: Intermittent claudication

If an answer is recorded in a box marked; no further questions need to be asked.

10. Do you get pain in either leg on walking?

____ Yes
____ No

11. Does this pain ever begin when you are standing still or sitting?

____ Yes
____ No

12. In what part of your leg do you feel it?

____ Pain includes calf/calves
____ Pain does not include calf/calves

If calves not mentioned, ask: Anywhere else?

13. Do you get it if you walk uphill or hurry?

____ Yes
____ No

Never hurries or walks uphill

14. Do you get it if you walk at an ordinary pace on the level?

____ Yes
____ No

15. Does the pain ever disappear while you are walking?

____ Yes
____ No

16. What do you do if you get it when you are walking?

____ Stop or slow down
____ Carry on

17. What happens to it if you stand still?

____ Relieved
____ Not relieved

18. How soon?

____ 10 minutes or less

____ More than 10 minutes

Diagnostic criteria for angina pectoris,
possible infarction and intermittent claudication

'Angina' is defined as being present in subjects who answer as follows:

Q.1 : 'Yes'
Q.2 or 3 : 'Yes'
Q.4 : 'Stop or slow down'
Q.5 : 'Relieved'
Q.6 : '10 minutes or less'
Q.7 : (a) Sternum (upper or middle, or lower), or
(b) left anterior chest and left arm

(If interviewing instructions are correctly observed throughout, it is sufficient to check the answer to Q.7.)

'Angina' may be graded according to severity:

Q.3 : 'No' = Grade 1
'Yes' = Grade 2

'Pain of possible infarction' is defined as being present in subjects who answer as follows:

Q.9 : 'Yes'

'Intermittent claudication' is defined as being present in subjects who answer as follows:

Q.10 : 'Yes'
Q.11 : 'No'
Q.12 : 'Includes calf'
Q.13 or 14 : 'Yes'
Q.15 : 'No'
Q.16 : 'Stop or slow down'
Q.17 : 'Relieved'
Q.18 : '10 minutes or less'

'Intermittent claudication' may be graded according to severity:

Q.14 : 'No' = Grade 1
'Yes' = Grade 2

Format of questionnaire

1. Closed and open ended questionnaire: Closed ended questionnaire are used in quantitative research (mostly in research related with medicine). They follow a format of closed ended questions (questions that can be answered by selecting the most appropriate option out of the given options). These can be scanned directly into a computer for performing further analysis easily and quickly.

Open ended questionnaires are used in qualitative research. They don't have a set of options to be selected as answers instead the respondent is given the freedom of writing the answer in his own words in the space provided. Open ended questionnaire is used in social and anthropological research. It is usually not recommended for use in medical research. The analysis of answers is complex and sometimes the respondent can deviate from the subject of the question.

2. Types of questions:

a. **Dichotomous questions:** The options to be selected as answer for the respective question are two (yes or no; agree or disagree; effective or ineffective). It is recommended to include a 'don't know' option as well.
b. **Multiple choice questions:** There are multiple choices given to be selected as answer.
c. **Rating scale:** The respondent may be asked to provide answers by grading the variable between two extremes. Example: Rate method 1, 2, 3 and 4 in sequence starting from the most effective to ineffective.
d. **Numerical answer:** example: asking the respondent to write his age

3. Language & style of word's use: This should be in accordance with the level of understanding of the respondents. Sometimes the questionnaire has to be translated into the language understood by the respondent. Leading questions, usage of professional terminology and abbreviations should be avoided.

4. Coding responses: The options to be chosen as answers may be provided with codes.

For example: What is the duration of your sleep during night in hours

1)8 2) 7 3) 6 4) 5

Sometimes the data can be collected through cascade format. The choice of following question depends on the option selected. Example:
Question 1.What is the duration of your sleep during night in hours?
1)8 2) 7 3) 6 4) 5
If answer is '4)' go to question 2
Question 2. Do you sleep during day?
1)Yes 2) No

5. Length of the questionnaire: The length of the questionnaire should not be long unless it suits the type of enquiry. The respondents will only complete those lengthy questionnaires which benefits their personal interests. Therefore the length of the questionnaire should be reasonable enough to not lose the interest of the respondent.

6. Reliability and validity of questionnaire: Reliability is the reflection of ability or quality of questionnaire whereas validity describes the consistency or the success of the questionnaire in performing the survey. There are two ways of ensuring the reliability:
a. in-built reliability: If certain questions are repeated, rephrased with the same response codes during the second survey the in-built reliability can be maintained.
b. repeat reliability: If the same questionnaire is re-employed on randomly chosen smaller size of the respondents repeat reliability can be achieved.
To maintain the validity of the questionnaire certain items may be cross checked. For example: checking the clinical records of the respondents may help in validating the questionnaire; a woman of 21 years cannot have a child of 13 years.

7. Order of the questions: It is very important to maintain a proper sequence of the questions because every question asked will sensitize the respondent and answers to the subsequent questions may become biased. For example: if a respondent is asked about the price of anti-hypertensive drugs he uses and subsequently asked to rate the effectiveness of the drug then the subsequent answer may be biased. Given below are some guidelines:

Scales:

The importance of standard measurement of concepts, opinions and attitudes cannot be ignored in research. A valid and standard measurement tool will help in interpreting the concepts and will ultimately decide the success of the research. There are different characteristics and conditions in health research such as health aspects, severity of diseases and attitudes, beliefs which are difficult to measure quantitatively. Since there is no mechanical tool to measure them a measurement tool called as scale is used. It is defined as a set of numbers or amounts assigned to measure the concepts, opinions and attitudes.

A researcher often comes across some characteristics which he can measure with a single survey item so he makes a judgment about the characteristic and assigns numbers to it. For example, if he wants to know whether a person chews tobacco, then he may ask a question "have you chewed tobacco in the past 30 days?" If the answer is yes, then the person is said to be a current tobacco chewer and a point is given to it.

There are some other characteristics which a researcher cannot measure using a single survey item. Therefore he designs questionnaires in such a way that the answers to each questions are assigned scores and all the scores are summed up to a final score which describes a characteristic.

Levels of measurement: There are four levels of measurement that are actually various categories of variables.

1. Nominal measurement: This is the most basic level of measurement done without assigning any quantitative value to variable. Instead the value assigned is just for identification or objectification of variables. Suppose a researcher is interested to know the effect of three different medicines in osteoarthritis. He wants to maintain the confidentiality of the medicines so he names these medicines as OA-1, OA-2 and OA-3.

2. Ordinal measurement: In this, the variables are arranged in order i.e., ranking of the variable is done. Although the ranks of variables are known the difference between the values of individual ranks is not know through ordinal measurement. For example, when it is said that India second most populous country after China, we understand that China ranks first and India ranks second in the list of most populous

countries but we cannot determine the difference between their populations from this statement.

3. Interval measurement: In this, we know the order as well as the difference between the individual variables. For example, while recording body temperature of a patient we know not just his body temperature but also the difference between his body temperature and the normal temperature of a human body. With interval measurement various statistical operations (mean, median, mode, standard deviation, etc) can be performed. But, there is no true zero in interval measurement. For example, there is no such thing as zero temperature i.e. there is no condition as zero heat or zero cold. Therefore, with interval measurement ratio cannot be calculated.

4. Ratio measurement: This measurement gives information about order, exact difference between variables and about zero point or absolute zero. Measurement of height and weight is done at ratio level.

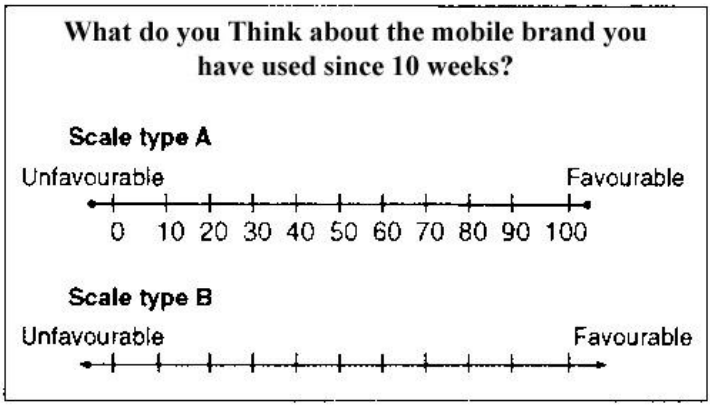
Rating Scales: (NTRUHS-April 2014)

In this, the respondent is asked to express an opinion qualitatively regarding aspects of objects, situations or traits of persons. Thus the respondent makes judgments about objects or describes his views about a characteristic by rating it in forms such as “poor, average, excellent” or always, occasionally, never” etc. The respondent is presented with options regarding a situation or trait and each option is assigned a degree or point on the scale. Thus, the rating scale measures qualitative variables quantitatively. Higher the number of points on the scale greater is the sensitivity of measurement. Generally, a three points or five points or seven points rating scale is used.

Rating scales are of two types. They are graphic rating scale and itemized or numerical rating scale.

Discrete or Itemized or numerical rating scale: In this scale, the statements or values about an object or situation or trait are arranged in a progressive order. The person rating it selects the most appropriate statement.

Continuous rating scale: In this type, different points are created on a continuous line and the person rating it is asked to select the most appropriate point. Sometimes the points on the scale are provided with descriptions as well.


What do you Think about the mobile brand you have used since 10 weeks?
Scale type A
Unfavourable
Favourable
0 10 20 30 40 50 60 70 80 90 100
Scale type B
Unfavourable
Favourable

Attitude scale: In this, the attitude of individuals towards a characteristic is determined. This is usually done by asking a closed ended question to the respondents. For example, the patients admitted in a hospital may be asked:

What is your attitude towards the cleanliness maintained in the hospital you are admitted?

a.Extremely positive b.Positive c.Uncertain d.Negative e.Extremely negative

In this way, the attitude of the patient towards the cleanliness in the hospital can be determined.

The problem with the attitude scale is that the attitude scale cannot be stated to measure the concepts exactly as they are meant to. It is so because the attitudes of the respondents change with their needs and requirements. For example, a respondent who is in need of a health service to a community may have a different attitude than an individual who does not need that service.

Types of attitude scale:

Summated rating scale or Likert scale: The scale is named after Likert who developed this scale. It consists of items which are considered to be having equal attitude value or importance or weightage. The responses to individual items are summed up at the end and final score is considered as the respondent's attitude.

Each item in this scale is itself an individual scale with different points. The basis of this scale that each item has equal weightage/ importance is considered as the main limitation of the scale because all items on a scale rarely have same weightage.

Thurstone scale or equally appearing interval scale: Developed by Louis Leon Thurstone, this was the first technique to measure attitude. Each statement in this scale has a dichotomous response option and unlike Likert scale each statement has different weightage. The mean score of all the statements is calculated and taken as the attitude of respondents.

The weight of individual statements is determined based on the scores assigned by judges. The Judges were asked to arrange the statements (which were presented to them in random order) in the order of most favourable to least favourable. Every adjacent statement in the scale has score value at equal intervals.

Guttman Scale: In this scale, the respondent is presented with a number of statements with dichotomous options (yes or no, agree or disagree). After every question specificity of the scale increases in such away that if the respondent agrees with a statement then it will mean that he agrees with all the previous statements. Further if the respondent does not agree with a statement then he will disagree with all the next statements.

Have you ever taken a pain killer in your life?	Yes	No
Have you taken a pain killer in last year?	Yes	No
Have you taken a pain killer in last month?	Yes	No
Have you taken a pain killer in last week?	Yes	No
Have you taken a pain killer today?	Yes	No

Standard Terminologies in Unani Medicine

1. WHO ICD 11 (International Classification of Diseases, 11th Revision):
This is a globally accepted system developed by the World Health Organization for coding diagnoses, symptoms, and procedures. It offers detailed disease classification and coding that enables uniform reporting in research and clinical settings. Using ICD 11 in Unani research standardizes disease terminology, facilitates data sharing, and enables comparison or integration with other health systems.

2. DSM V (Diagnostic and Statistical Manual of Mental Disorders, 5th Edition):
Published by the American Psychiatric Association, DSM V classifies mental health conditions with specific diagnostic criteria. When Unani research involves psychiatric or psychosomatic conditions, DSM V terminology complements traditional classifications and supports standardization in research.

3. NAMASTE (National AYUSH Morbidity and Standardized Terminologies):
NAMASTE is a framework developed in India to provide standardized morbidity codes, data sets, and terminologies specifically for AYUSH systems (which include Unani). It integrates traditional diseases and conditions with modern classification to promote uniform documentation, research, and health statistics.

4. BIS Standards (Bureau of Indian Standards for Unani Medicines):
The BIS frames quality standards for Unani medicines, covering raw materials, manufacturing practices, safety, efficacy, and labeling to ensure product quality and safety. These standards are crucial for quality control, especially in research evaluating pharmacological and therapeutic outcomes.

5. CCRUM Standards (Central Council for Research in Unani Medicine):
The CCRUM, a government body in India, sets research guidelines, clinical protocol standards, and validation criteria for Unani medicines and practices. CCRUM standards integrate traditional concepts with scientific methods, promoting evidence-based research and quality assurance in Unani.

Methodology in Unani Medicine Research

Study Design:

- Clearly specify the research type: clinical trial (randomized controlled trial preferred), observational study, preclinical study (in vitro, in vivo), or literary research.
- Define control groups, placebo, or comparative interventions if applicable.
- Duration of the study and follow-up periods detailed.

Intervention Protocol:

- Exact description of how the Unani formulation is administered.
- Treatment regimen timeline and monitoring adherence protocols.

Assessment and Evaluation Methods:

- Use classical Unani diagnostic criteria: pulse examination, mizaj (temperament) evaluation, signs and symptoms scoring based on Unani disease concepts.
- Employ validated scoring systems for symptom improvement.
- Biochemical, hematological, or imaging investigations as applicable, incorporating modern scientific parameters to substantiate findings.
- Use quantitative and qualitative assessments to measure efficacy and safety.

Data Collection and Management:

- Baseline data collection before intervention.
- Periodic assessment schedules (e.g., weekly, monthly).
- Standardized forms or electronic data capture tools for recording clinical and laboratory observations.
- Monitoring for adverse effects or complications.

Quality Control and Standardization:

- Ensure reproducibility in drug preparation and administration.
- Calibration of instruments and adherence to Good Clinical Practice (GCP) guidelines.
- Training of personnel in Unani diagnostic and therapeutic protocols.

Statistical Analysis:

- Selection of appropriate statistical tests (e.g., paired t-test, ANOVA, chi-square) depending on data type and study design.
- Predefine significance levels (commonly $p<0.05$).
- Use of software for data analysis (e.g., SPSS, R).

Ethical Considerations:
- Obtain approval from relevant ethics committees.
- Ensure informed consent and confidentiality.
- Compliance to national and institutional research standards.

By combining classical Unani diagnostics and therapeutics with robust clinical research design, the materials and methodology provide a clear blueprint ensuring scientifically credible and culturally authentic research. This approach supports evidence generation while preserving the holistic essence of Unani medicine.

Factors affecting the research results

There can be two types of factors that can affect the research results, the first one is the factor that the investigator wants it to affect the research results whereas the second one is the factor which the investigator does not want it to affect the research results. When the second type of factor affects the research results the results of the study don't represent the phenomenon it claims to represent; hence the validity of the research is affected. For example, sometimes when a particular investigation is replicated under a different condition and setting or on different participants the results tend to differ. When both the studies are compared it may realized that some factors distorted the results in the former study without the realization of the investigator. Therefore to perform a valid research it is very important to control the factors that affect the validity of the research. These factors are classified as those affecting external validity and those effecting internal validity. Even before knowing these factors it is better to understand what do external and internal validity mean.

External validity:

It is the extent to which the findings of the research can be applied to the general population, normal setting and times. For example a drug that is tested in laboratory may fail to be effective in normal individuals; a study done on made could not be generalized to female population.
External validity is of two types

1. Population validity
2. Ecological validity

1. Population validity: It explains the extent to which the results of investigation can be generalized from sample to the population from which the sample is taken. Population validity explains whether the sample drawn is a representative of the population or not and also upto what extent personal variables (age, sex, etc) are in interaction with one another.
2. Ecological validity: It describes the extent to which the results of an investigation can be generalized from research settings to normal settings

Factors affecting external validity:

1. **Selection bias interacting with the intervention:** The selection of the study group is biased hence result produced by the intervention or the treatment is biased.
2. **Pretest sensitization:** Sometimes pretesting elevates the sensitivity of the participants and they behave in unnatural ways thus altering the validity of the research.
3. **Post-test sensitization:** Sometimes post-test limits the validity of research
4. **Multiple treatment interference:** When the participants are exposed to multiple treatments the results don't reflect only the desired treatment. This happens when the participants involved in the study seek treatment apart from the treatment given in the study.
5. **Hawthorne effect:** Mere awareness that the individuals are participants in a study makes them behave differently which alters the result.
6. **Experimenter effect:** Sometimes when a particular investigators gives intervention there is a change in the outcome.

Internal validity:

It is the extent to which the result of the study can be attributed to the independent variable and not to any other variable.

Factors affecting internal validity:

1. **History:** An unexplained event occurring during the study can alter the result. For example, a shortage of certain drugs used in treatment regime will interrupt the supply; ultimately the study will be discontinued.
2. **Maturation:** physiological and psychological changes occurring in the participants such as growing older (in pediatric and geriatric studies), becoming depressed alters the results independently.
3. **Testing:** A repeat measurement of certain findings carries the effect of previous measurement. For example, the participants may tend to compete with the findings of the previous test when repeat test is done as they have gain familiarity with the test. This produces a different reading without any existing difference.
4. **Instrumentation:** A faulty instrument will record a false reading and hence alters the result.

5. **Regression towards the mean:** Selection of individuals with extreme scores as participants affects the results because when the core is re-recorded over a period of time it tends to regress towards the mean.
6. **Differential selection:** The assignment of the participants to the study and control group is flawed in a way that both the groups are not comparable. Matching or randomization should be done to avoid this.
7. **Attrition:** Some of the participants drop out of the study due to certain factors. For example, the controls may be demoralized on not receiving the intervention and ultimately drop out from the study.
8. **Design contamination:** Sometimes the participants may intend to make the research a success or a failure thereby contaminating the research design. Therefore the investigator must interview the participants after the conclusion of the study to rule out any contamination.

Bias:

It is a systematic error which distorts the results and prevents the researcher from finding the truth. Unlike in literal meaning, bias may not a deliberate action in the research. Bias affects the results making them deviate from the truth such that the results are either over-estimated or under-estimated. Thus it has a direction of deviation. In this way it is different from random error which occurs because of chance and has no direction of deviation.

A number of biases have been described by the experts but only the most common biases are described in the following.

1. Selection bias

The selection bias arises when there is distortion in the results of the study due to a particular way of selection of the participants. It is said to exist when the selected sample is not a representative of the population. The way of selection of participants is done such that it produces distortion of the results. This is said to be the most common type of bias in observational and experimental studies.

a. Prevalence-incidence bias

Also called as Neyman bias, prevalence-incidence bias occurs in case control studies when there is significant time lag between exposure and the investigation. Because of this, the cases that have either died or recovered are missed. This exclusion of the cases due to recovery or death may under estimate or over estimate the results.

b. Berkson's bias

This bias is named after Berkson who first described it. Sometimes the participants with two different conditions are taken under study. It is more likely that the first condition may not compel the patient to consult the doctor until a severe second condition arises. For example, an alcoholic may not consult the doctor for alcoholism until severe complications arise due to alcohol consumption.

Berkson bias arises when the selection of the participants is compelled by the exposure and the outcome. For instance, it was concluded after some studies that there is strong association between oestrogen and endometrial cancer. However it was later explained that oestrogen caused endometrial cancer to be diagnosed as it induced

uterine bleeding compelling the patients to seek medical help. The selection of the participants was biased as it was compelled by the uterine bleeding

c. Non-response bias:

At times, the individuals selected during the sampling may not or cannot participate in the study. Non-response bias occurs when the respondents are different from the non-respondents regarding the exposure. As a result of the non-participation of previously selected individuals some other individuals are roped in as the participants causing non-response bias. If the non-response bias is equally present in the cases and the controls then the bias may not significantly affect the results. A large sample size minimizes the non-response bias.

2. Information bias:

This is also called as misclassification or ascertainment bias. It arises when the collection or measurement of information is done inaccurately.

a. Diagnostic bias: Diagnostic bias occurs when the knowledge about the association of an exposure with an outcome influences the diagnosis. It is said that if a pathologist is aware of a patient being alcoholic then he may more likely deem the liver specimen as “alcoholic liver cirrhosis”. Similarly, in a case-control study the knowledge about an association between an exposure and an outcome may compel the investigator to perform more rigorous diagnostic tests among the exposed group. Thus, the chances of detecting the outcome becomes higher among the exposed than in non-exposed only due to the rigorous testing.

b. Memory or Recall Bias: In some studies, the accuracy of the study is largely dependant on the ability of a participant to recall the events. It is quite possible for human beings not to remember events occurring in the past accurately. Sometimes, the memory about an event may be distorted due to some other event. Thus, there occurs a recall bias due to inaccurate recalling of the events. This is more common in case control study as the entire study is conducted retrospectively. Recall bias can be minimized by collecting the data from work records or medical records.

Errors in research

These are mistakes or inaccuracies that arise at various stages of the research process, affecting the validity, reliability, and integrity of findings. These errors are broadly classified into sampling errors and non-sampling errors, each with specific types and causes.

Common Types of Research Errors:

Sampling Errors:

These arise due to the sample selected not truly representing the target population. This might occur through chance or poor sampling technique and can be minimized, but not always eliminated, by improving sampling methods.

Population Specification Errors:

Occur when the researcher fails to clearly define and select the appropriate group for the study. If the target population is ambiguous or inconsistently specified, findings become unreliable.

Selection Errors:

Happen when certain groups are inadvertently included or excluded during participant selection, which can lead to biased and unrepresentative results.

Non-Response Errors:

Result when a significant portion of selected participants do not respond or participate. The views and characteristics of non-respondents may differ from those who engage, skewing results and reducing generalizability.

Measurement Errors:

These arise when differences exist between what is observed and the true values, stemming from issues like poorly calibrated instruments, inconsistent procedures, or subjective measurement techniques.

Questionnaire and Interview Errors:

Includes poorly worded, biased, or confusing questions that lead to misunderstood or inaccurate responses. Errors can also arise when

questions are not conveyed properly by interviewers or when the collection instruments (surveys, forms) are unclear or inconsistent.

Processing and Recording Errors:
Mistakes during data entry, coding, or analysis—such as typographical errors or misinterpretation of responses—can alter datasets and subsequent conclusions.

Errors in Problem Definition and Research Design:
If a study lacks a clear research question or defines a problem poorly, it may pursue irrelevant, unanswerable, or trivial objectives, leading to wasted effort and weak results.

Methodological Errors:
Using research or statistical methods that do not match the research question, or favoring methods simply because the researcher is more comfortable with them rather than because they are appropriate for the problem.

Analytical and Interpretation Errors:
Faulty or inappropriate data analysis methods, incorrect statistical techniques, or misinterpretation of results can yield invalid or misleading conclusions.

Blind Data Mining:
Collecting data indiscriminately, without a clear plan or purpose, and then searching for possible patterns later. Without a guiding hypothesis, this often produces unreliable findings.

Reporting and Documentation Errors:
Inadequate reporting of methods, vague writing, or omission of crucial details impedes reproducibility and can lead to misinterpretation by others.

Other Notable Errors:

Ethical Violations:
Failing to obtain ethical approvals, not reporting conflicts of interest, or ignoring participant rights and confidentiality.

Favoring Research Fads:

Choosing trendy but fleeting research topics that may not sustain scientific relevance by the publication time.

- Unresearchable or Weak Research Questions:

Framing problems that are too vague or not answerable with scientific methods.

Prevention and Minimization:

Errors can be minimized through careful planning, clear definition of objectives, rigorous design, proper training, use of validated tools, pretesting instruments, meticulous record-keeping, and transparency in reporting.

Caveats: Some degree of non-sampling error is inevitable in complex research, but recognizing and addressing potential pitfalls early in the process can greatly improve research quality and trustworthiness.

Analysis and interpretation of results in research

Analysis and interpretation of results in research are crucial steps where collected data is examined to extract meaningful insights and then explained to understand their significance in relation to the research question.

What is Analysis & Interpretation of Results?

- Analysis of Results is the systematic application of statistical and/or logical techniques to describe, summarize, and compare data collected during the study. It involves organizing, processing, and applying appropriate statistical tests or qualitative methods to reveal patterns, relationships, or differences.

- Interpretation of Results goes beyond just presenting numbers or themes. It is about explaining the meaning and implications of the analyzed data in the context of the research objectives, existing theories, and other studies. Interpretation attempts to answer "What do these results mean?" and "How do they relate to the hypothesis or research question?" It also considers alternative explanations, limitations, and the broader relevance of the findings.

How is it Done? Step-by-Step

1. Data Preparation and Cleaning

- Check for missing data, outliers, or errors.
- Organize data logically for analysis.
- Transform or code data if needed (e.g., categorizing qualitative data).

2. Data Analysis

- For Quantitative Research:
  - Use descriptive statistics (means, frequencies).
  - Conduct inferential statistics (t-tests, ANOVA, regression) to examine relationships or differences.
  - Employ software tools like SPSS, R, or Excel for calculations.
- For Qualitative Research:
  - Use methods like thematic analysis, content analysis, or discourse analysis.
  - Code data into categories or themes.
  - Identify patterns, narratives, or underlying constructs.

3. Interpretation

- Reasonably explain relationships found in the data.
- Connect findings to the research hypothesis and objectives.
- Compare results with previous studies and theoretical frameworks.
- Consider extraneous or confounding factors that might influence results.
- Provide a logical explanation for unexpected findings.
- Reflect on practical implications of findings.
- Acknowledge limitations and the scope of applicability.

4. Validation

- Sometimes seek expert opinions or peer review of interpretations to avoid bias.
- Triangulate findings using multiple methods or data sources when possible.

5. Presentation

- Summarize findings clearly using tables, charts, and narrative.
- Write interpretation in the discussion section of the research report or paper.

Detailed Example

Suppose you conducted a clinical trial testing a Unani formulation Safoof-e-Muhazzil on obese patients with phlegmatic temperament to reduce body weight.

Analysis:

- Collect body weight data at baseline, 1 month, and 3 months.
- Calculate mean weight loss for treatment and control groups.
- Use paired t-tests to compare weight before and after treatment within groups.
- Use independent t-tests to compare mean weight loss between groups.
- Check for statistical significance (e.g., $p < 0.05$).

Interpretation:

- If treatment group shows a significant mean weight loss compared to control, interpret that the Unani formulation effectively reduces weight in this population.
- Relate this to the hypothesis predicting restoration of humoral balance leading to improved metabolism.
- Discuss how findings align or contrast with previous Unani and biomedical research on weight management.
- Consider whether factors like diet or physical activity could have influenced results.
- Address limitations such as sample size or study duration.
- Suggest that this supports the traditional use of *Safoof-e-Muhazzil* and warrants larger trials.

Analysis involves applying appropriate techniques to process data and reveal patterns or differences, while interpretation involves making sense of these findings in relation to your research questions, existing knowledge, and practical implications. Together, they provide the evidence base that supports or refutes your hypothesis, guiding conclusions and further research directions.

Research conclusions

Research conclusions are the final section of a research paper where you summarize the key findings, synthesize the main points, and explain the significance and implications of your study. A well-written conclusion provides closure, reinforces the research objectives, and highlights the contributions your research has made. It may also suggest recommendations for future research or practical applications, leaving readers with a clear understanding of what was learned and why it matters.

Method of Writing Research Conclusions

1. Restate the Research Problem or Aim

Begin by briefly restating the research problem, aim, or hypothesis in a fresh way that reflects the depth of your study.

2. Summarize Key Findings

Concisely summarize the main results or outcomes, focusing on how they answer your research questions or support/refute your hypothesis. Avoid repeating details already covered; synthesize key insights instead.

3. Explain the Significance

Discuss the importance of your findings – how they contribute to existing knowledge, their practical or theoretical implications, and relevance to the field.

4. Address Limitations (optional but recommended)

Acknowledge any limitations or constraints in your study to demonstrate critical reflection and transparency.

5. Suggest Future Research

Propose directions for further investigation that can build on your work or address remaining questions.

6. End with a Strong Closing Statement

Finish with a thought-provoking idea, recommendation, or call to action that underscores the importance of your study.

Applying This to the Previous Example (Research on Safoof-e-Muhazzil in Obese Patients with Phlegmatic Temperament)

A sample conclusion based on the example of testing the Unani formulation Safoof-e-Muhazzil could be:

Conclusion

This study investigated the effect of daily administration of Safoof-e-Muhazzil on body weight reduction and humoral balance restoration in obese patients with phlegmatic temperament over three months. The findings demonstrated a statistically significant decrease in body weight and improvement in phlegmatic symptoms compared to the control group, supporting the hypothesis that the formulation helps restore humoral equilibrium in alignment with Unani theory.

These results highlight the potential of Safoof-e-Muhazzil as an effective traditional therapy for obesity linked to phlegmatic temperament, bridging classical Unani principles with modern clinical evidence. However, limitations such as sample size and study duration suggest caution in generalizing findings.

Future research with larger cohorts and longer follow-up is warranted to confirm these benefits and to explore the formulation's mechanisms further. Ultimately, this work contributes to evidence-based integration of Unani medicine into contemporary healthcare practices.

This conclusion restates the aim, summarizes results, explains their significance within both Unani and modern scientific contexts, acknowledges limitations, and suggests future research, fulfilling the method of writing an effective research conclusion

Reporting of Research

This is the final and a very important step in the process of the research. The researcher communicates with the audiences about the research work through the report; hence he needs to maintain a good quality, clarity and honesty while preparing the report. The format differs according to the type of publication in which the report will be presented.

Uniform requirements for manuscripts submitted to biomedical journals: In 1978, editors of major medical journals realized that the currently prevalent 250 styles of writing reports prevalent at that time needed to be unified into only a single standard style. With this idea they met at Vancouver, Canada and framed technical requirements for publishing manuscripts called as "uniform requirements for manuscripts submitted to biomedical journals". Within a short span of time, the style was adopted by many journals and authors and the Vancouver group was called International Committee of Medical Journal Editors (ICJME). The ICJME revises the recommendations regularly providing a base for ethical standards in biomedical research reporting and publishing beyond the manuscripts as well. ICJME recommendation is now called as "Recommendations for conduct, reporting, editing and publication of scholarly work in medical journals" (ICJME recommendations), which was revised in 2016.

Often a report pertaining to observational and experimental studies is categorized as introduction, Methods, Results and discussion (IMRAD), but this format is not mandatory. There are usually sub-categories under these categories to organize the content further. There are specific reporting guidelines for specific types of research. For example, STROBE statement (STrengthening the Report of OBservational studies in Epidemiology) provides guidelines for reporting observational studies; CONSORT statement (CONsolidation Standards Of Reporting Trials) provides guidelines for reporting randomized trials. A brief overview of general guidelines provided by ICJME for writing report is as follows:

a. Title page: In this, information about the author and the article is presented as article title, author information, disclaimer (if any), sources

of support, word count and sometimes the number of tables and figures.

b. Abstract: This is should be a brief but comprehensive reflection of the research giving information about the context or background for the study, purpose of the study, procedures (selection of study participants, settings, measurements, analytical methods), main findings and conclusions. Different journals have different formats for structured abstracts and they should be followed as advised.

c. Introduction: Background or context of the study, objective of the study, hypothesis tested should be stated in the introduction.

d. Methods: This section should give the reasons for conducting the study in a particular way. This section highlights the information that was at hand when the plan or protocol was being designed while information gained during the study is to be included in the results section. A statement about approval or exemption from the research ethics committee is also mentioned in methods. If there is no ethics committee then it should be mentioned that research followed the principles of the Declaration of Helsinki. The information about consulting or contracting an organization while conducting the research is to be mentioned in detail. Selection and description of participants, technical information, and statistics should also be included as sub-sections.

e. Results: Results in the form of text, figures and tables should follow a logical sequence without repeating every data in different forms and emphasizing only the most important information. Numerical results including the derivatives and calculation of the derivatives and their statistical significance should be given. Data regarding demographic variables (age, sex, etc) are reported separately.

f. Discussion: This section is to be commenced by summarizing the main findings and explaining them. New and important aspects of the study, implications for further research, and limitations of the study should be stated. Association of variables (age, gender, etc) and difference between statistical and clinical significance, link between conclusion and goal of the study should be described.

Chapter 7. Databases and Portals of Unani Medicine

Unani medicine, with its roots in ancient Greco-Arabic medical tradition, has secured a significant presence in India and worldwide. As the field continues to grow, the infrastructure supporting research and academic study has also expanded, leveraging digital platforms and databases to increase accessibility, visibility, and collaboration. This comprehensive review delves into the major databases and portals relevant to Unani medicine—including those focused exclusively on Unani, those supporting the broader AYUSH spectrum (Ayurveda, Yoga, Unani, Siddha, and Homeopathy), and global multidisciplinary academic indexes.

1. DHARA (Digital Helpline for Ayurveda Research Articles)

DHARA is a pioneering digital initiative primarily designed to index research articles in Ayurveda but also holds relevance for those researching Unani medicine and other Indian traditional systems. Developed to address the lack of systematic digital access to research outputs, DHARA provides a unique and central resource for published articles that might otherwise be scattered across regional and less accessible journals.

Key Features

- Comprehensive Indexing: DHARA indexes thousands of research articles published across more than 4,100 journals, covering both national and international platforms. While its focus is Ayurveda, it includes interdisciplinary research pertinent to Unani medicine.
- Bridging Gaps in Access: Many research papers in Unani and related fields are published in minor or regional journals not indexed by global databases. DHARA fills this accessibility gap, offering a searchable platform for practitioners and researchers.
- Evidence-Based Practice Facilitation: By aggregating literature, DHARA supports evidence-based practices and systematic reviews, helping researchers identify gaps and opportunities in traditional medicine studies.
- User-Friendly Search Tools: DHARA allows filtered searches based on topics, journals, authors, and publication years, enhancing research efficiency.

Strategic Importance
DHARA's collation of diverse publications helps the Unani community bolster scientific credibility, provides a platform for meta-analysis, and brings Indian traditional medicine into mainstream academic discourse.

2. AYUSH Research Portal
The AYUSH Research Portal, maintained by the Ministry of AYUSH, Government of India, acts as a centralized resource for research in all AYUSH systems—including Unani medicine.

Key Features

- Multidisciplinary Coverage: The portal encompasses Ayurveda, Yoga, Naturopathy, Unani, Siddha, Homeopathy, and Sowa Rigpa.
- Knowledge Dissemination: Researchers can access current research updates, search for AYUSH terminology, browse journals, and locate clinical/pre-clinical studies, drug research, and fundamental research.
- Abstract Submission: Allows registered users to submit research abstracts, facilitating engagement and updating the knowledge base.
- Comprehensive Database: Enables detailed search options across disciplines, diseases, drugs, and clinical trials, specifically supporting Unani research dissemination alongside other Indian medicine systems.

Strategic Importance
The portal supports collaboration, keeps practitioners updated with the latest research, and is a key resource for students, policy-makers, and the general public seeking reliable AYUSH research information.

3. UGC-CARE (Consortium for Academic and Research Ethics)
The UGC-CARE list is an initiative from the University Grants Commission (UGC) to ensure quality, ethical academic publications across disciplines—including Unani medicine.

Key Features

- Curated Journals List: The UGC-CARE list provides a vetted and periodically updated directory of academic journals, ensuring only credible, peer-reviewed publications are recognized.
- Discipline-Specific Resources: Notable Unani journals in the UGC-CARE list include the Hippocratic Journal of Unani Medicine and publications from the Central Council for Research in Unani Medicine.
- Academic Recognition: Publications in UGC-CARE listed journals are considered for faculty appraisal, research evaluation, and regulatory compliance.

Strategic Importance
UGC-CARE directly influences the quality and integrity of academic research in Unani medicine, discouraging predatory publishing and standardizing research outputs for academic recognition and career progression.

4. PubMed
PubMed, maintained by the U.S. National Library of Medicine, is one of the largest and most comprehensive biomedical literature databases worldwide. While not specific to Unani medicine, PubMed serves as a significant repository for peer-reviewed research in traditional medicine, including Unani.

Key Features
- Global Reach: PubMed indexes articles from journals across the world, aiding international access and collaborations.
- Unani Research Indexing: Hundreds of Unani-related studies—ranging from pharmacological analysis to clinical trials—are available, broadening the evidence base.
- Systematic Reviews: Supports systematic reviews by offering advanced searching and citation features.
- Reliability: The majority of indexed papers meet stringent peer review and publication standards.

Strategic Importance
Presence in PubMed increases the international visibility of Unani research, ensures adherence to global publication standards, and promotes cross-cultural scientific dialogue.

5. Scopus

Scopus is a multidisciplinary indexing service from Elsevier, widely regarded for its rigorous curation and expansive coverage of academic literature, including Unani medicine and allied health sciences.

Key Features

- Comprehensive Coverage: Includes journals, books, and conference proceedings across all science domains.
- Citation Analysis: Enables analysis of article impact, authorship trends, and collaborative networks.
- Recognized Journals: Certain Unani and AYUSH journals are indexed in Scopus, often highlighted in UGC-CARE listings.
- Advanced Metrics: Provides citation counts, H-indexes, and altmetric scores, which facilitate research assessment.

Strategic Importance

Scopus inclusion signals journal quality, enhances individual and institutional reputations, and enables comparative analysis of global research trends in Unani medicine.

6. NAMASTE Portal

The NAMASTE (National AYUSH Morbidity and Standardized Terminologies Electronic) Portal was established by the Ministry of AYUSH as a centralized digital health platform for all AYUSH systems, including Unani medicine.

Key Features

- Morbidity Data Collection: Collects and standardizes disease data across AYUSH practitioners, enabling evidence-based health analytics.
- Standardized Terminologies: Implements dual coding and standardized morbidity codes tailored to Unani and other Indian systems for uniformity and clarity.
- Electronic Health Records: Promotes adoption of electronic patient data, facilitating research and administrative planning.
- Policy Formulation: Allows policy-makers and researchers access to real-time morbidity statistics for national health planning.

- Integration and Interoperability: Supports integration with national health information systems (e.g., SNOMED-CT), enhancing the visibility of Unani medicine globally.

Strategic Importance
NAMASTE acts as a bridge between traditional and modern healthcare paradigms, demonstrating the effectiveness of Unani medicine through data-driven approaches and enabling research based on robust, standardized health data.

7. A-HMIS (Ayush Hospital Management Information System)
A-HMIS is a scalable, digital platform implemented for the streamlined management of AYUSH hospitals, including Unani centers and research institutions.

Key Features
- Hospital Digitization: Enables electronic capture and storage of patient records—from OPD/IPD management to prescription and billing.
- Research Support: Facilitates easy extraction of anonymized clinical data for retrospective studies and quality audits.
- Resource Optimization: Improves workflow, helping in resource allocation, scheduling, and inventory management.
- Stakeholder Engagement: Links practitioners, administrators, and researchers for collaborative program development and monitoring of healthcare delivery.

Strategic Importance
The A-HMIS is crucial for modernizing AYUSH institutions, integrating Unani medicine into the larger digital health environment of India, and aiding quality research via organized electronic data.

8. Other Relevant Portals and Resources

CCRUM (Central Council for Research in Unani Medicine)
- CCRUM maintains its own repositories of research, including journals, monographs, and mobile apps that guide clinical practice, inform about temperament, present treatment guidelines, and introduce Unani formulations.

- Contributes terms and clinical codes to international vocabularies like SNOMED-CT, enhancing global interoperability and facilitating integration with world health records.

Ayush Next Portal

- A digital platform focused on career guidance, educational content, and interactive forums to foster the new generation of Unani practitioners and researchers.

Comparative Table: Major Databases and Portals for Unani Medicine

Database/Portal	Focus Area	Accessibility	Notable Features	Coverage for Unani Medicine
DHARA	Ayurveda, related Indian systems	Open access	Extensive indexing, gap analysis, research support	Indirect/interdisciplinary
AYUSH Research Portal	All AYUSH systems incl. Unani	Open access	Research updates, literature, clinical/preclinical trials	Comprehensive
UGC-CARE	Academic journals (all disciplines)	Journal-specific	Quality control, recognized list, career impact	Dedicated Unani journal lists
PubMed	Biomedical sciences	Open access	Global visibility, peer-reviewed, citation/collaboration tools	Select Unani research indexed
Scopus	Multidisciplinary scholarly content	Subscription	Citation metrics, analytics, advanced search	Select AYUSH & Unani journals
NAMAS	AYUSH	Restricted/S	Disease	High, with

TE Portal	morbidity & terminology standards	emi	coding, real-time data, policy support	Unani specific codes
A-HMIS	AYUSH hospital operations	Restricted	Patient record digitization, research support, data security	Increasingly adopted for Unani

Challenges and Opportunities in Using Digital Resources

Challenges

- Language Barriers: Older Unani research often appears in regional languages and is not indexed in international databases, requiring special efforts for digitization and translation.
- Standardization of Terms: Multiple terminologies for diseases and therapies have historically hampered data aggregation; recent coding initiatives (e.g., NAMASTE) are closing this gap.
- Data Integration: Legacy, manual record systems pose obstacles to efficient data capture—A-HMIS seeks to modernize these processes.
- Quality Control: UGC-CARE and international indexing services aim to curb unethical publishing and improve the standard of research.

Opportunities

- Meta-Analyses and Reviews: Centralized resources like DHARA and AYUSH Research Portal enable comprehensive reviews, identifying trends and gaps in evidence.
- Policy and Public Health Planning: NAMASTE and A-HMIS provide real-time, aggregated morbidity and hospital operation data, guiding resource allocation and planning.
- Global Reach and Collaboration: Inclusion in PubMed, Scopus, and international standards (e.g., SNOMED-CT) opens up Unani medicine for global scientific engagement.

Conclusion

The digital transformation of research infrastructure for Unani medicine and the broader AYUSH sector has enabled a new era of visibility, evidence-based practice, and interdisciplinary collaboration. Platforms like DHARA and the AYUSH Research Portal facilitate discovery and synthesis of research; registers like UGC-CARE and global databases such as PubMed and Scopus ensure research credibility and reach; while government-backed initiatives (NAMASTE, A-HMIS) standardize, digitize, and integrate Unani medicine into national and global health frameworks. These developments not only enhance research quality and clinical practice but also position Unani medicine as a recognized participant in the global healthcare ecosystem.

This review captures the current digital ecosystem supporting Unani medicine. Continuous engagement with these evolving resources is essential for advancement in academic research, clinical evidence-gathering, and policy planning in traditional medicine.

Chapter 8. Guidelines for Reporting Research: Overview and Key Types

Clear, transparent, and standardized reporting is essential for research to be understood, critically appraised, and reliably used in clinical practice or further scientific work. Reporting guidelines are structured tools—usually in the form of checklists or flow diagrams—that ensure authors include all vital information concerning the planning, conduct, analysis, and results of their studies. Adhering to these guidelines improves the reproducibility, transparency, and reliability of research outcomes.

What Are Reporting Guidelines?

A reporting guideline is a systematically developed checklist, flow diagram, or structured text outlining the minimum information that should appear in a research manuscript. The aim is to:

- Enable readers to fully understand what was planned, done, and found.
- Allow replication by other researchers.
- Facilitate use in systematic reviews and clinical decision-making.
- Minimize biases by giving a transparent account of methodology and results.

Most major biomedical journals and publishers require compliance with relevant reporting guidelines during submission to ensure rigor and completeness.

Why Are Reporting Guidelines Important?

- Promote clarity and completeness of research reports.
- Ensure critical appraisal is possible, revealing study strengths and limitations.
- Improve global scientific standards and trust in published findings.
- Help avoid selective reporting or "outcome switching" by requiring disclosure of protocol deviations and pre-specified methods.

How to Use Reporting Guidelines

1. Identify your study design: Each guideline is tailored for specific study types.
2. Consult the relevant checklist before writing, during study design, and throughout manuscript preparation.
3. Follow each item: Ensure all recommended elements are addressed in your paper.
4. Attach the completed checklist when submitting to journals, as increasingly required by publishers.

Commonly Used Reporting Guidelines (by Study Type)

Study Design	Recommended Guideline	Key Features
Randomized Controlled Trials (RCTs)	CONSORT	25-item checklist, flowchart for participant flow
Systematic Reviews/Meta-analyses	PRISMA	27-item checklist, flow diagram for study selection
Observational Studies (cohort, case-control, cross-sectional)	STROBE	22-item checklist focused on study design/reporting
Case Reports	CARE	Checklist for necessary details in patient cases
Diagnostic Accuracy Studies	STARD	Checklist for test evaluation studies
Animal Preclinical Studies	ARRIVE	Reporting for animal research transparency
Prognostic Studies	TRIPOD	Reporting multivariable prediction models
Quality Improvement Studies	SQUIRE	Reporting quality enhancement initiatives
Study Protocols	SPIRIT, PRISMA-P	Reporting planned methods and analysis
Web-based Surveys	CHERRIES	Checklist for online survey studies

Other extensions exist for subtypes, such as genetic association studies (STREGA, an extension of STROBE) and reporting sex and gender (SAGER guidelines).

Key Elements in Reporting Guidelines

Most checklists require the following core sections to be clearly reported:

- Title/Abstract: Accurate description of study design and scope.
- Introduction: Rationale and objectives.
- Methods: Study design, settings, participants, data collection, interventions, statistical analysis, and protocol deviations.
- Results: Participant flow, baseline data, outcomes, adverse events, and findings.
- Discussion: Interpretation, limitations, and implications.
- Funding/Conflicts of Interest: Full disclosure of study sponsorship and potential biases.

Where to Find Reporting Guidelines

- EQUATOR Network: The leading global resource, it hosts comprehensive lists of guidelines for all study types, in multiple languages.
- Major journals and publisher websites often highlight links and require relevant checklists at submission.

Reporting guidelines are central to high-quality science. They offer a reproducible framework to ensure that every piece of research—whether an RCT, observational study, systematic review, or case report—can be critically assessed, trusted, and built upon by future researchers and health professionals. Consistent use of these guidelines is now a basic expectation for publication in most reputable scientific outlets.

PRISMA guidelines for conducting reviews

The PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) guidelines provide a standardized framework for reporting systematic reviews and meta-analyses, aiming to ensure transparency, completeness, and reproducibility in the review process. Updated in 2020, the PRISMA statement is widely regarded as the gold standard for reporting in health and related sciences.

Key Components of PRISMA Guidelines

1. 27-Item Checklist

- The PRISMA 2020 statement centers on a 27-item checklist , which serves as a step-by-step set of recommendations for authors. Each checklist item addresses a point in the review process: from rationale and objectives, search strategy, eligibility criteria, study selection process, data collection methods, risk of bias assessment, synthesis methods, results, and interpretation of findings.
- The checklist is designed to be comprehensive and applies to all sections of a systematic review, including the title, abstract, introduction, methods, results, discussion, and funding sources. This ensures clarity and allows peers, editors, and readers to assess the rigour and credibility of the review.

2. Flow Diagram

- PRISMA includes a flow diagram that visually maps the screening and selection process for studies. The diagram tracks the number of records identified, screened, excluded, and included at each stage—providing a transparent account of how studies move through the review.
- There are templates for new reviews, updates, and those including sources beyond electronic databases.

3. Protocol Registration

- PRISMA encourages registering the review protocol (e.g., in PROSPERO) before starting the review. This pre-registration enhances clarity, helps avoid duplication, and minimizes risk of reporting bias.

Steps and Best Practices for Conducting Reviews using PRISMA

A. Planning and Protocol Development

- Develop a focused research question, often structured using frameworks such as PICO (Population, Intervention, Comparison, Outcome) for intervention reviews, or other relevant models (e.g., PECO, SPIDER).
- Draft and register a protocol outlining inclusion criteria, databases to be searched, and planned methods for synthesis and bias assessment.

B. Literature Search and Study Selection

- Conduct comprehensive searches across multiple databases and sources, including grey literature, with explicit search strategies documented for reproducibility.
- Apply clearly defined eligibility criteria for selecting studies.

C. Data Extraction and Risk of Bias Assessment

- Extract relevant data systematically as outlined in the protocol, using piloted forms or software tools.
- Evaluate the risk of bias in included studies with recognized tools.

D. Synthesis and Reporting

- Present findings using the PRISMA checklist as a guide for each section.
- Use the flow diagram to document and visualize the selection process for transparency.
- Summarize the evidence, discuss limitations, and present implications for practice and research.

E. Reporting in Manuscript

- Ensure all PRISMA checklist items are addressed in the manuscript (title, abstract, background, methods, results, discussion, funding).
- Include both the completed PRISMA checklist and flow diagram as part of the submission package for transparency and compliance.

Importance and Impact

The PRISMA guidelines are internationally endorsed. Adhering to them:

- Improves the credibility and reproducibility of systematic reviews.
- Helps authors, editors, peer reviewers, policy makers, and practitioners understand, evaluate, and apply the findings with confidence.
- Facilitates clearer synthesis, more reliable decision-making, and ultimately stronger evidence-based practice and policy.

Supplemental Tools

- The checklist and flow diagram can be completed online or with dedicated apps, enhancing user-friendliness and standardization across reviews.

PRISMA Extensions

- Specialized PRISMA extensions exist for particular review types (diagnostic, scoping, network meta-analyses, etc.), ensuring methodological nuances are addressed for each context.

In summary, the PRISMA guidelines provide the structure, clarity, and accountability necessary for systematic reviews and meta-analyses to fulfill their role in evidence-based fields . Strict adherence to PRISMA is now a key expectation for publication and is central to high-quality synthesis in clinical and health sciences.

STROBE Guidelines: Strengthening the Reporting of Observational Studies in Epidemiology

STROBE (STrengthening the Reporting of OBservational studies in Epidemiology) is an internationally developed set of recommendations aimed at improving the completeness, transparency, and quality of reporting in observational research. Specifically, it addresses the three main types of analytical epidemiological studies:

- Cohort studies
- Case-control studies
- Cross-sectional studies

Purpose of STROBE

- Enhances clarity and transparency : Ensures research readers understand what was planned, done, found, and how to interpret the findings.
- Supports critical appraisal : Provides detailed information so that strengths and weaknesses can be accurately assessed.
- Standardizes reporting : Encourages a uniform structure, making it easier for editors, reviewers, and readers to evaluate and compare studies.

The STROBE Checklist

The STROBE statement comprises a checklist of 22 essential items that authors should include in their reports. The checklist covers six main sections:

Section	Examples of Key Checklist Items
Title/Abstract	Indicate study design; provide a summary of methodology and principal findings
Introduction	State the background/rationale and study objectives
Methods	Describe study design, participants, variables, data sources, bias, sample size, statistical methods
Results	Report participants, descriptive and outcome data, main findings, other analyses
Discussion	Discuss key results, limitations, interpretations, and generalizability
Funding	Disclose sources of funding and any role of funders

- 18 items are common to all three study types.
- 4 items have specific variants depending on whether a study is a cohort, case-control, or cross-sectional design[2].

How STROBE Improves Reporting

- Ensures completeness : By following each checklist item, essential design and results information is less likely to be omitted.
- Facilitates synthesis : Standardized reporting is crucial for systematic reviews and meta-analyses.
- Enhances validity : Enables assessment of study reliability, bias, and generalizability by requiring detailed methodological disclosures.

Applications and Endorsement

- Widely endorsed by leading biomedical journals and required for submission in many cases.
- Extensible: Specialized versions exist for fields such as genetic epidemiology and nutritional epidemiology.

Not Prescriptive for Study Design

STROBE provides guidance on how to report —not how to design or conduct—observational research. Its checklist is not a tool for assessing study quality, but for ensuring thoroughness and transparency in manuscripts.

Core Principles Promoted by STROBE

- Transparency
- Completeness
- Reproducibility

Summary Table: STROBE's Essential Features

Feature	Description
Scope	Cohort, case-control, cross-sectional studies
Checklist Length	22 items
Focus	Reporting completeness and transparency
Journal Endorsement	Supported by hundreds of biomedical journals

Extensions Available	For various specialized fields and study types

- The STROBE checklist and its explanation/documentation are freely available through official project and EQUATOR Network websites, ensuring researchers can access detailed guidance and examples.

STROBE is foundational for high-quality, standardized reporting of observational studies. Adhering to its checklist benefits authors, journals, and readers by promoting transparency, critical appraisal, and reliable knowledge dissemination in epidemiological research.

CONSORT Guidelines: Overview and Purpose

The CONSORT(Consolidated Standards of Reporting Trials) guidelines are internationally recognized standards designed to improve the quality and transparency of reporting in randomized controlled trials (RCTs) across all fields of health research. Developed by the CONSORT Group, these guidelines aim to ensure that essential information about trial design, conduct, analysis, and interpretation is consistently and clearly reported, facilitating critical appraisal, reproducibility, and evidence synthesis.

Key Objectives

- Enhance transparency and completeness in reporting RCTs.
- Reduce bias arising from incomplete or selective reporting.
- Facilitate interpretation and replication of published trial findings.
- Streamline systematic reviews and meta-analyses by ensuring standardized presentation of trial data.

Main Components of the CONSORT Statement

1. Checklist

The CONSORT checklist provides a comprehensive list of essential reporting items. As of the latest update (CONSORT 2025), it comprises 30 items , while earlier versions offered 25. The checklist covers all critical elements needed for transparent trial reporting and is structured across the main sections of a research article:

Section	Checklist Focus
Title and Abstract	Identifying the article as a randomized trial; structured summaries of design, methods, findings
Introduction	Scientific background, rationale, and objectives
Methods	Detailed trial design, participants, interventions, outcomes, randomization, blinding, sample size
Results	Participant flow, recruitment, baseline data, numbers analyzed, outcomes, harms
Discussion	Interpretation, limitations, and generalizability
Other Information	Protocol registration, funding sources, conflicts of interest

2. Participant Flow Diagram
A recommended flow diagram visually presents the progress of all participants through the trial, from enrollment, allocation, and follow-up to analysis. This ensures readers can easily track participant numbers and exclusions at each stage, clarifying how the final analysis dataset was derived.

3. Extensions
CONSORT offers multiple extensions to address unique reporting needs for trials with specific designs (e.g., cluster-randomized, non-inferiority, or equivalence trials), types of interventions (such as herbal or non-pharmacological treatments), different data outcomes (like harms or abstracts), and special populations.

Key Principles Promoted by CONSORT
- Clarity and completeness : Full details on design, protocol changes, interventions, setting, and results.
- Transparency of methods , especially concerning randomization, blinding, and statistical analyses.
- Disclosure of pre-specified outcomes versus those actually reported, supporting research integrity.
- Full reporting of harms and adverse events , not just efficacy.

Importance in Modern Research
- Most major journals require CONSORT compliance for all submitted RCT reports, making it a cornerstone of high-quality clinical trial publication.
- CONSORT's focus on transparent reporting improves trial reproducibility, systematic review accuracy, and the reliability of the clinical evidence base.
- The guidelines are periodically updated to reflect advances in trial methodology and reporting expectations; the most recent version, CONSORT 2025, expands further on data sharing and outcome reporting.

Resources and Support
- The CONSORT website (www.consort-statement.org) hosts up-to-date checklists, flow diagrams, explanations, and guidance documents.

- Joint initiatives such as the CONSORT-SPIRIT collaboration offer training and templates for researchers, editors, clinicians, and even patients.

Summary Table: CONSORT Essentials

Feature	Description
Standardization	Checklist ensures all RCTs report key methodological and result details
Transparency	Clear reporting on randomization, blinding, sample size, outcomes
Applicability	Used worldwide; required by numerous leading journals
Updates & Extensions	Regularly revised; specific extensions for various trial designs, interventions, outcomes

The CONSORT guidelines are fundamental to the ethical and rigorous reporting of randomized controlled trials. By promoting clarity, completeness, and transparency, CONSORT strengthens the evidence base for clinical practice and research, supports reproducibility, and helps maintain high scientific standards across health disciplines.

ARRIVE Guidelines: Reporting Standards for Animal Research

The ARRIVE guidelines(Animal Research: Reporting of In Vivo Experiments) provide a standardized checklist for reporting animal research to improve transparency, reproducibility, and rigor in preclinical studies. Developed by the NC3Rs (National Centre for the Replacement, Refinement & Reduction of Animals in Research), ARRIVE aims to ensure that all critical aspects of animal experiments are disclosed in publications, allowing for accurate interpretation, evaluation, and reproducibility.

Key Elements of the ARRIVE Guidelines

The ARRIVE 2.0 guidelines consist of two sets of recommendations:

1. Essential 10: The minimum information that must be included in every manuscript:

-Study design: How groups were allocated, experimental unit, and controls.
-Sample size: Numbers per group and rationale for sample size.
-Inclusion/exclusion criteria: Criteria for including/excluding animals/data and reasons for exclusions.
-Randomization: How subjects were assigned to groups.
-Blinding: Whether and how blinding was used throughout the study.
-Outcome measures: Clearly defined primary and secondary outcomes.
-Statistical methods: Details for all statistical analyses.
-Experimental animals: Species, strain, sex, age, provenance, and health status.
-Experimental procedures: What, how, when, where, and why of all experimental interventions.
-Results: Summary data for each group, including all measures, variability, and effect sizes.

2. Recommended Set: Additional items that further support transparent reporting, such as:

- Animal housing and husbandry details.
- Ethical statement and approvals.
- Data accessibility.

- Interpretation and scientific context.
- Protocol registration and relevant conflicts of interest.

Importance and Impact

- Improves reproducibility: Detailed methods enable other researchers to repeat and validate findings.
- Reduces bias: Transparent reporting of randomization, blinding, and sample size calculation limits selective reporting and improves scientific integrity.
- Ethical responsibility: Comprehensive reporting maximizes the knowledge gained from animal use, supporting the 3Rs (Replacement, Reduction, Refinement).

Usage

Most reputable journals and funding agencies now require compliance with ARRIVE for manuscripts describing animal experiments.

Summary

The ARRIVE guidelines are the gold standard for reporting animal-based preclinical research. Adhering to ARRIVE improves scientific quality, transparency, and ethical standards in biomedical research involving animals.

CARE Guidelines: Reporting Standards for Case Reports

The CARE guidelines (CAse REports) are international consensus-based standards developed to improve the quality, transparency, and usefulness of medical case reports. These guidelines provide a 13-item checklist for authors, ensuring that all necessary information is included for clarity and reproducibility in clinical case reports.

Purpose and Rationale

- Enhance accuracy, transparency, and completeness in published case reports.
- Facilitate the sharing of detailed clinical findings to inform practice, education, and research.
- Ensure case reports are useful in expanding medical knowledge and highlighting unique clinical scenarios.

Key Components of the CARE Checklist

The CARE checklist addresses each section of a case report, guiding authors through the essential elements that should be presented:

Section	Description
Title & Keywords	The diagnosis or intervention of primary focus, plus the words "case report"; 2-5 keywords specifying the case topics
Abstract	Summarizes what is unique about the case, main concerns, diagnoses, interventions, outcomes, and primary take-away lessons
Introduction	Brief explanation of why the case is unique with literature context
Patient Information	De-identified demographic data, main concerns, symptoms, relevant medical/family/psychosocial history, past interventions
Clinical Findings	Summary of significant physical exam and clinical findings
Timeline	Organized account of relevant historical and current information, preferably as a figure or table
Diagnostic Assessment	Methods (PE, labs, imaging), challenges, reasoning (differential diagnosis), and prognosis where applicable
Therapeutic	Types and details of intervention (e.g., dosage,

Intervention	duration), changes and rationale
Follow-up and Outcomes	Clinician/patient-assessed outcomes, follow-up findings, adherence, tolerability, adverse events
Discussion	Strengths and limitations, comparison with available literature, rationale for conclusions, main take-away lessons
Patient Perspective	When relevant, a statement from the patient about their experience
Informed Consent	Confirmation that informed consent was obtained from the patient

Why Use CARE Guidelines?

- Improves clarity : Ensures all relevant details are presented so readers can understand, interpret, and apply the information in practice or research.
- Reduces bias : Structured reporting minimizes omissions, selective reporting, and enhances clinical relevance.
- Supports publication : Many journals require compliance with CARE for submitted case reports, promoting global standards in medical publishing.

Additional Resources

- The CARE guidelines are available in multiple languages and endorsed by numerous journals and publishers.
- Online tools, such as CARE-writer, assist authors in producing compliant reports and include interactive checklists for completion.

Summary

The CARE guidelines provide a comprehensive, standardized framework for reporting clinical case reports. By following its checklist, authors contribute high-quality evidence, helping translate individual experiences into shared learning for the wider medical community.

Chapter 9.
Intellectual Property Rights (IPR), Patents, and TKDL in Unani Medicine

Introduction

Unani medicine, one of the world's oldest systems of traditional medicine, has contributed remarkably to healthcare through its holistic approaches and pharmacopeia. In the globalized era, where knowledge travels internationally, safeguarding the core innovations and traditional remedies of Unani requires robust legal and statutory frameworks. The concepts of Intellectual Property Rights (IPR), patents, and the Traditional Knowledge Digital Library (TKDL) have thus emerged as essential tools to protect, nurture, and promote Unani medicine in the modern world.

This report explores the scope and significance of IPR, patent law, and the pivotal role of TKDL in ensuring the protection and sustainable development of Unani medicine, supporting innovation while preventing misappropriation.

Understanding Intellectual Property Rights (IPR) in Unani Medicine

What are IPRs?

Intellectual Property Rights (IPRs) refer to the legal rights that result from intellectual activity in the industrial, scientific, literary, and artistic fields. For Unani medicine, these rights are crucial for:

- Protecting traditional knowledge from unauthorized use and exploitation
- Encouraging innovation by granting exclusive rights to inventors
- Ensuring fair benefit sharing among knowledge holders
- Providing recognition and respect for centuries-old wisdom

Types of Relevant IPRs

Several forms of IPRs are applicable in the context of Unani medicine:

- Patents: For new, innovative, and industrially applicable formulations or processes
- Trademarks: Identification of products, proprietary medicines, or institutions

- Geographical Indications (GI): Protection of products whose qualities are linked to their geographical origin
- Copyrights: For literary works such as treatises, textbooks, and databases
- Trade Secrets: Protection of undisclosed formulas, processes, or methods

Significance of Patents in Unani Medicine

What are Patents?

A patent is an exclusive legal right granted for an invention, which must be novel, involve an inventive step, and be capable of industrial application. In the context of Unani, patents can be granted for:

- New dosage forms
- Improved extraction processes
- Novel combinations of known drugs
- Modified release systems

Importance of Patents

- Encouragement of Research and Development (R&D): Patents provide a monetary incentive and market exclusivity, leading to increased investment in Unani medicine research.
- Standardization and Quality Control: Patent requirements push researchers and companies to standardize formulations and processes, improving product reliability and reputation.
- Commercialization and Economic Growth: Patent holders can license their inventions, enabling industrial scale-up and export, thus boosting economic prosperity in the Unani sector.
- Attracting International Collaborations: Recognized patents act as portfolios for partnerships with global healthcare and pharmaceutical industries, integrating Unani with mainstream medicine.
- Protecting Against Biopiracy: By securing patents, innovations in Unani medicine are guarded against misappropriation and unauthorized patent claims abroad.

Challenges in Patenting Unani Medicine

While patents are beneficial, traditional knowledge often struggles to fit into conventional patent frameworks because:

- Much of Unani knowledge is already documented or in public domain, lacking novelty.
- Many remedies are based on communal or inherited knowledge, making individual patent claims complicated.
- The requirements for scientific validation and novelty can be hurdles for patenting traditional remedies.

Cases like the patenting attempt on turmeric and neem for their wound-healing and antifungal properties highlighted global concerns about biopiracy and the inadequacies of existing patent laws in protecting traditional medical knowledge.

Role and Scope of the Traditional Knowledge Digital Library (TKDL)
What is TKDL?
The Traditional Knowledge Digital Library (TKDL) is a landmark initiative by the Government of India, especially significant for the Unani system. It acts as a searchable online database of documented traditional medical knowledge, including Unani, Ayurveda, and Siddha[7][8][9].

Purpose of TKDL:

- Prevents misappropriation: Ensures that Unani formulations cannot be wrongly patented by others who claim them as new inventions
- Bridges language barriers: Makes Unani knowledge accessible to international patent examiners by translating several classic texts into global scientific languages
- Supports defensive protection: Provides evidence of “prior art” to defeat wrongful patent claims worldwide

Structure and Functioning
- TKDL has classified the Indian traditional medicine systems into several thousand subgroups, including vast Unani formulations.
- For Unani, more than 112,500 formulations from classical Urdu, Arabic, and Persian texts have been cataloged and verified by experts.
- TKDL is integrated with international patent offices, enabling examiners to conduct prior art searches in native languages and thereby prevent illegitimate patents.

Global Recognition

The World Health Organization (WHO) has recognized TKDL's pivotal role in digitizing and safeguarding traditional medical systems. The digitization project, powered by artificial intelligence, ensures that knowledge in Unani and other systems isn't misused and can support both research and preservation.

The Importance of IPR for Researchers and Practitioners in Unani

Protection and Preservation of Traditional Knowledge

- Safeguarding Heritage: IPR measures protect the collective wisdom of Unani practitioners and communities from misuse and wrongful appropriation, ensuring it is respected and preserved.
- Documenting Knowledge: Initiatives like TKDL have led to systematic documentation, reducing the risk of loss or plagiarism of ancient knowledge.

Promotion of Responsible Innovation

- Incentivizing Innovation: By granting rights and incentives, IPR frameworks encourage researchers to innovate within the Unani tradition, developing improved products, therapies, and technologies.
- Quality Assurance: The process of preparing for IP protection often involves rigorous scientific study and standardization, which enhances safety and efficacy in Unani medicines.

Fair Benefit Sharing

- Recognition and Rewards: Proper IPR management allows for fair distribution of benefits to original knowledge holders—communities, practitioners, and researchers.
- Prevention of Biopiracy: By establishing legal and digital proof of prior art, systems like TKDL prevent biopiracy and ensure that benefits arising from Unani innovations are justly shared from local to international levels.

Building a Global Profile for Unani Medicine

- Increasing Global Acceptance: The patenting and documentation of Unani innovations help establish credibility in

the global medical community, leading to greater acceptance and integration with modern practices.

- Expanding Commercial Opportunities: With appropriate IP protection, Unani medicines can be commercialized internationally, capturing new markets and connecting with diaspora and new patient populations.

Legal Frameworks: National and International

Indian Legal Framework

- The Indian Patent Act: Amended to include provisions that prevent patenting of traditional knowledge in the public domain, while allowing patents for genuinely novel inventions in Unani. Indian law aligns with the need to both protect TK and incentivize new inventions.
- Protection under Biodiversity Law: The Convention on Biological Diversity and India's Biological Diversity Act also ensure TK holders' rights and prevent the unauthorized use of biological resources.

International Context

- WIPO and Global Collaboration: The World Intellectual Property Organization (WIPO) acknowledges the necessity of integrating IP law with the protection of traditional knowledge, ensuring that originating communities benefit from commercialization and advances.
- Defensive and Positive Protection: TKDL and national systems employ both forms: offering documentation to block illegitimate patents (defensive) and avenues for the communities to exploit their knowledge for economic benefit (positive).

Challenges and Future Perspectives

Key Challenges

- Reconciling Traditional and Modern Frameworks: The collective and ancient nature of Unani knowledge often contradicts the individualistic, novelty-driven patent systems.
- Documentation and Digitalization Gaps: While progress is rapid, there remains a wealth of oral and undocumented knowledge in Unani needing careful collection and protection.

- Regulatory Hurdles: Ensuring compliance with safety, efficacy, and quality standards for global patents is demanding and resource-intensive.

Future Directions

- Expanding TKDL Coverage: More comprehensive documentation of regional and lesser-known Unani practices is needed.
- Community Engagement: Involving traditional practitioners and communities in IPR processes ensures authenticity and fair benefit-sharing.
- International Advocacy: Greater collaboration with global bodies will help cement defensive and positive protections for Unani medicine.
- Integrating Modern Science: Continued R&D, backed by IPR, can build bridges between tradition and contemporary healthcare, increasing the scientific validation of Unani medicine.

Case Studies and Real-World Examples

Example Patents

- New Unani Compositions: Recent patents have been granted for processes such as the preparation of a novel Unani composition "Jigirina" used for the treatment of viral hepatitis and jaundice.
- Optimization of Traditional Formulas: Enhancements in the extraction and concentration processes of classic Unani remedies like "Khamira" have led to effective, scientifically validated modern medicines now protected under patent laws.

Defensive Actions and Success Stories

- Turmeric and Neem Cases: Internationally contested, these patent revocation instances highlighted the importance of documentation and defensive IPR, much of which helped inspire the creation of TKDL.
- TKDL's Global Role: The database has successfully defeated hundreds of wrongful patent applications, demonstrating its value in upholding Indian traditional medical heritage on the world stage.

Conclusion

The scope and significance of IPR, patents, and the TKDL in Unani medicine are profound and wide-ranging. Robust IP protections preserve Unani knowledge, foster responsible innovation, prevent misappropriation, and ensure the equitable sharing of benefits among stakeholders. Patents and digital knowledge systems like TKDL are not threats but allies of tradition, supporting global recognition, scientific advancement, and long-term viability of Unani practices.

For researchers, practitioners, entrepreneurs, and policymakers, deep engagement with IPR issues is essential to harnessing the full potential of Unani medicine—safeguarding its roots while nurturing its future in a rapidly changing world.

Chapter 10. Research Critique

Concept of Research Critique

Research critique is the systematic, objective, and detailed evaluation of a research study, examining its strengths and weaknesses to assess the credibility, relevance, and applicability of its findings. It involves:

- Review and analysis of the study's design, methodology, data collection, analysis, and interpretation .
- Judging the value, scientific rigor, and applicability of research, particularly in translating evidence into clinical practice.
- Ensuring that only high-quality, trustworthy evidence informs clinical decisions and public health strategies in fields such as Unani medicine.

Purpose:

- To verify that research findings are valid, reliable, and applicable to the target population.
- To identify methodological gaps, potential biases, and limitations, thus improving future research quality.
- To assist practitioners in making evidence-based decisions by recognizing the strengths and shortcomings of existing literature.

Research Critique

A research critique differs from a simple critique. It requires:

- Understanding the rationale behind the study: Why was this study needed? What gap does it address?
- Detailed scrutiny of the purpose and objectives, the significance of the topic, and the rationale for selecting specific methodologies.
- Evaluation of the research question or hypothesis : Is it clearly defined, focused, and relevant to practice?
- Contextual analysis: How does the study relate to prior work (through an effective literature review)? Does it contribute new, useful knowledge?

Effective critique helps:

- Expose flaws that may not be evident at first glance.

- Establish whether the study's conclusions can be generalized or should be treated cautiously.
- Facilitate the translation of evidence to clinical settings, improving health outcomes and guiding policy in systems like Unani medicine.

Critically Evaluating a Research Article in Health and Unani Research

Evaluating research articles—especially in health sciences and Unani research—requires a structured, critical approach. Below are the key steps and criteria commonly used:

1. Initial Screening: Scope and Relevance

- Assess Title and Abstract: Check if the study addresses a significant health or Unani research question and fits your area of interest.
- Purpose and Objectives: Ensure the study's aims are clearly stated and are relevant to health/Unani medicine policy, practice, or scientific advancement.

2. Evaluation of Scientific Rigor

A. Study Design

- Appropriateness: Does the design fit the research question (e.g., randomized control trial, observational, case series)? In Unani studies, are traditional clinical approaches or modern methods (like HPTLC fingerprinting, standardization) used appropriately?
- Ethics: Has the study received ethical approval? Is patient consent obtained? This is crucial for studies involving Unani formulations or therapies, especially with herbo-mineral drugs.

B. Methodology

- Sample Selection: Is the sample size justified? Are the inclusion/exclusion criteria well-defined?
- Intervention/Procedure: Are Unani drugs/formulations described in sufficient detail (e.g., dosage, preparation)? Are methods standardized for reproducibility?

- Controls and Randomization: For clinical or pharmacological Unani research, are there appropriate comparison or control groups?

3. Data Analysis and Interpretation

- Statistical Analysis: Are statistical methods valid and suitable for the data type? For Unani research, is there integration of modern statistical evaluation with traditional results?
- Outcome Measures: Are the primary and secondary outcomes clinically meaningful and clearly defined?
- Results Presentation: Are findings presented clearly, with appropriate tables/figures, and are limitations discussed?

4. Evaluation of Results and Conclusions

- Validity and Reliability: Do the results logically follow from the data? Are methods shown to be valid (e.g., safety and efficacy, pharmacognostical evaluation for Unani drugs)?
- Bias and Confounding: Are sources of bias, confounding variables, or external influences discussed?
- Safety Considerations: Are adverse effects and safety findings reported, which is critical in herbal and herbo-mineral Unani research?

5. Relevance to Practice or Policy

- Applicability: Can findings be implemented in clinical practice or Unani health systems?
- Transferability: Is there a discussion on the transferability of results to different populations or settings?
- Innovations/Contributions: Does the article contribute new knowledge or validation to Unani therapeutics or health systems?

6. Transparency and Quality of Reporting

- Peer Review: Confirm if the article is published in a peer-reviewed journal, especially relevant in Unani research, which is guided by bodies like CCRUM and AYUSH.
- Conflict of Interest and Funding: Are conflicts and funding sources clearly stated, ensuring unbiased reporting?

- References and Citations: Are sources current, credible, and correctly cited?

7. Specific Considerations for Unani Research

- Traditional Evidence Integration: Does the study integrate Unani principles (Ilaj-bil-Tadbeer, Ilaj-bil-Dawa), texts, or pharmacopoeia with modern clinical or laboratory techniques?
- Standardization: Are processes for the standardization of Unani drugs/formulations explained and validated?
- Safety and Toxicity: Are there thorough safety and toxicity evaluations of Unani therapies, given the use of complex mixtures and minerals?

8. Ethical and Regulatory Compliance

- Adherence to Regulatory Bodies: Does the study align with guidelines from AYUSH, CCRUM, and other relevant authorities?
- Registration and Protocol: Was the clinical trial registered, and protocol reviewed by competent bodies?

9. Final Appraisal and Synthesis

- Overall Quality: Weigh evidence using established criteria—relevance, coherence, effectiveness, efficiency, impact, and sustainability[8][14].
- Process Evaluation: For complex interventions, assess not only outcomes but implementation procedures, contextual factors, and fidelity to the intervention.

The evaluation of health—and particularly Unani—research articles is a nuanced process that includes standard scientific criteria, integration of traditional knowledge, rigorous methodology, ethical compliance, and a focus on safety and practical relevance. Critical engagement at each step ensures that only high-quality, relevant, and reliable research informs practice and policy in Unani medicine and the wider health sciences.

Bibliometrics

Bibliometrics are quantitative measures used to evaluate the impact and influence of scientific publications, researchers, and journals based on citation data and related metrics. Here's an explanation of the major bibliometric indicators, with real-world examples and context:

Impact Factor (IF)

- Definition: Measures the average number of citations received per article published in a journal during the preceding two years. It is widely used to gauge the prestige of academic journals.
- How it works:

For example, if the journal Nature had an Impact Factor of 42 in 2022, it means that, on average, its articles published in 2020 and 2021 were cited 42 times in 2022.

- Calculation:

Suppose Journal X published 100 articles in 2020 and 2021. In 2022, articles from those two years were cited 400 times.

Impact Factor = 400 citations / 100 articles = 4.0.

- Use: Higher IF suggests greater significance in its field, but it only reflects journal-level influence, not the quality of individual articles.

h-index

- Definition: A metric that attempts to measure both the productivity and citation impact of the publications of a scientist or scholar.
- How it works:

If a researcher has an h-index of 10, it means they have published at least 10 papers that have each been cited at least 10 times[6].

- Example:

Dr. Smith has published 15 papers.

- 8 have 20 citations each,
- 3 have 10 citations each,
- 4 have fewer than 10 citations.

Dr. Smith's h-index is 11 because 11 papers each have been cited at least 11 times, but not 12.

- Use: Used for evaluating individual researchers, departments, or even universities, but is best for comparison within the same field or career stage.

i-10 Index

- Definition: The number of academic publications an author has written that have been cited at least 10 times. Introduced by Google Scholar.
- How it works:

Dr. Jane Doe has written 37 papers. If 22 of them have each been cited at least 10 times, her i-10 index is 22.

- Use: Simple metric to quickly see how many of a researcher's outputs have had a moderate citation impact; mainly used within Google Scholar profiles[6].

CiteScore

- Definition: Similar to the Impact Factor, but typically calculated based on a three- or four-year publication window and uses all document types indexed in Scopus.
- How it works:

Imagine Journal Y has published 180 articles in the last three years. In the current year, all of these articles have been cited a total of 720 times.

- CiteScore = 720 citations / 180 articles = 4.0.
- Difference from IF: CiteScore's longer time window and inclusion of all content types (including reviews, conference papers, etc.) can offer a more comprehensive view than the Impact Factor.

Real-world Applications and Cautions

- For researchers: These metrics help in selecting journals to publish in or demonstrate their impact for grants, hiring, or promotion.
- For journals: A high Impact Factor or CiteScore attracts more submissions and can increase prestige.
- Cautions: Metrics can vary greatly depending on the source (Web of Science, Scopus, or Google Scholar), are discipline-dependent, and may be subject to manipulation. Therefore,

they should always be supplemented with qualitative assessments such as peer review and personal statements.

Summary:

- Impact Factor reflects journal influence.
- h-index measures researcher productivity and impact.
- i-10 index indicates how many of a researcher's works have moderately high citation counts.
- CiteScore offers an alternative, comprehensive journal metric over a broader time window.

Interpreting these numbers in context—like comparing within similar research fields and career stages—is critical for meaningful evaluation.

Reference formats

Reference formats are standardized systems for citing sources in academic writing, ensuring that readers can locate the original materials and authors receive proper credit for their ideas. The choice of referencing style often depends on the academic discipline, journal, or institutional preference. Here's a descriptive overview of the most widely used referencing styles, how they work, and where they are primarily applied:

1. **APA (American Psychological Association) Style**
   - Usage: Predominant in psychology, education, and other social sciences.
   - System: Author-date. In-text citations include the author's surname and the year of publication, for example: (Smith, 2020).
   - Reference list: Placed at the end of the document, with entries in alphabetical order by the surname of the first author. Each entry includes: Author(s), Year, Title, Source, and sometimes a DOI.
   - Distinctive features: APA omits the place of publication in its latest edition and relies heavily on digital object identifiers (DOIs) for journal articles.

2. **MLA (Modern Language Association) Style**
   - Usage: Commonly used in humanities, especially English studies, literature, and related fields.
   - System: Author-page. In-text citations provide the author's surname and page number: (Smith 23).
   - Works Cited page: Entries list author, title, container (e.g., journal or book title), publisher, year, and page numbers, presented in a strict order.
   - Distinctive features: Focuses on page numbers rather than years, which emphasizes textual evidence over recency.

3. **Harvard Style**
   - Usage: Widely used in a variety of academic disciplines, particularly in the UK, Australia, and business/social sciences globally.

- System: Author-date, similar to APA, but formatting details vary. In-text citation appears as (Smith, 2009).
- Reference list: Author(s), Year, Title, Publisher, Place of publication. Harvard can vary between institutions or publishers, so always check local guidelines.
- Distinctive features: Flexible and adapted by many universities; no single universal version.

4. Chicago Style

- Usage: Frequently used in history, arts, and some social science subjects.
- System: Two main options:
- Notes and bibliography: Uses numbered footnotes or endnotes for in-text citations and a full bibliography.
- Author-date: Similar to Harvard, with in-text citations like (Smith 2010, 22).
- Bibliography: Includes all cited works and additional readings.
- Distinctive features: Unique for offering both the footnote system and author-date system, providing flexibility for different types of texts and preferences.

5. Vancouver Style

- Usage: Standard in biomedical, health, and natural sciences.
- System: Numeric. In-text citations appear as numbers in brackets or superscript, corresponding to a numbered reference list: e.g., (1).
- Reference list: Ordered by the sequence of appearance in the text, not alphabetically. Each entry typically includes author(s), article title, journal, year, volume, page numbers.
- Distinctive features: Designed for brevity and clarity in clinical and scientific writing.

6. IEEE Style

- Usage: Preferred in engineering, computer science, and technology fields.
- System: Numeric, similar to Vancouver. Citations are numbers in square brackets, e.g., [7].
- Reference list: Listed in order of first appearance. Entries have standardized abbreviations for journals and conferences.

- Distinctive features: Very concise, often used for conference papers and technical reports, with specific rules for electronic sources.

Key Points Across All Styles:

- Consistency is crucial: Always use the same style throughout a document and follow specific guidelines for that style.
- Components of a reference: Usually include author name(s), title of the work, source/journal/book, year, and page numbers or DOI.
- Choosing a style: Based on the academic field, institutional guideline, or journal requirement. For example, APA is common in psychology, MLA in literature, IEEE in engineering, and Vancouver in medicine.

Proper referencing not only lends credibility to your work but also helps avoid plagiarism and allows readers to verify or further explore your sources.

Details of Vancouver style:

International Committee of Medical Journal Editors (ICJME) recommendations states that the citing of the references should be in accordance with the rules published in National Library of Medicine (NLM)'s "Citing Medicine 2nd Edition".

Vancouver style or citation by the reference number system recommends that the references should be cited in the order in which they appear in the material published.

Citing Books:

The citing of a book should follow the order and punctuations as shown below:

Name of the Author. Title. Edition. Place of publication: Publisher; Date of publication. Pagination.

Single author or editor

Name of the Author. Title. Edition. Place of publication: Publisher; Date of publication. Pagination.

Editor's name, editor. Title. Edition. Place of publication: Publisher; Date of publication. Pagination.

Two or more authors or editors:
Name of first Author, name of second author. Title. Edition. Place of publication: Publisher; Date of publication. Pagination.
Name of first editor, name of second editor. Title. Edition. Place of publication: Publisher; Date of publication. Pagination.

No author:
Title. Edition. Place of publication: Publisher; Date of publication. Pagination.
HIV/AIDs resources: a nationwide directory. 10th ed. Longmont (CO): Guides for Living;
c2004. 792 p.

Multiple volumes:
Author. Title. Edition. Volume. Place of publication: Publisher; Date of publication. Pagination.

Book with author(s) and editor(s)/translator(s) illustrator(s)
Name of the Author. Title. Edition.Name of editors, editor. Place of publication: Publisher; Date of publication. Pagination.
Martin EW. Hazards of medication. 2nd ed. Ruskin A, Napke E, Alexander S, Kelsey FO,
Farage DJ, Mills DH, Elkas RW, editors. Philadelphia: Lippincott; 1978. 686 p.

Name of the Author. Title. Edition. Name of the translator,translator. Place of publication: Publisher; Date of publication. Pagination.
Stein E. Anorectal and colon diseases: textbook and color atlas of proctology. 1st Engl. ed.
Burgdorf WH, translator. Berlin: Springer; c2003. 522 p.

Name of the Author. Title. Edition. Name of the translator and editor ,translator and editor. Place of publication: Publisher; Date of publication. Pagination.
Richer PM. Artistic anatomy. Hale RB, translator and editor. New York: Watson-Guptill; 1971.

255 p.

Name of the Author. Title. Edition. Name of the translator,translator ; Name of the editor, editor. Place of publication: Publisher; Date of publication. Pagination.
Luzikov VN. Mitochondrial biogenesis and breakdown. Galkin AV, translator; Roodyn DB,
editor. New York: Consultants Bureau; 1985. 362 p.

Book with organization as author/editor
Name of the organization. Title. Edition. Place of publication: Publisher; Date of publication. Pagination.
Advanced Life Support Group. Acute medical emergencies: the practical approach. London:
BMJ Books; 2001. 454 p.

Name of the organization,editor. Title. Edition. Place of publication: Publisher; Date of publication. Pagination.
Swiss Pharmaceutical Society, editor. Index nominum: international drug directory. 18th ed.
Stuttgart (Germany): Medpharm Scientific Publications; 2004. 1823 p.

Book title in a language other than English:
Name of the Author. Title. Edition. Place of publication: Publisher; Date of publication. Pagination. Language.
Katsunori K. [Euthanasia and criminal law]. Shohan. Tokyo: Seibundo; 2003. 198 p. Japanese.

Book with text in multiple languages:
Name of the Author. Title. Edition. Place of publication: Publisher; Date of publication. Pagination. Languages.
Puig-Samper MA, Ruiz R, Galera Andres A, editors. Evolucionismo y cultura: darwinismo en
Europa e Iberoamerica. Aranjuez (Spain): Ediciones Doce Calles; 2002. 407 p. Spanish,
English, French, Portuguese.

Citing journals:

The citing of a journal and article published in it should follow the order and punctuations as shown below:

Standard journal article:
Name of the Authors. Article title. Journal title. Date of publication; Volume (issue) : Pagination.
Petitti DB, Crooks VC, Buckwalter JG, Chiu V. Blood pressure levels before dementia. Arch
Neurol. 2005 Jan;62(1):112-6.

Journal article with many authors:
Name of the first Author, Name of the second author, Name of the third author. Article title. Journal title. Date of publication; Volume (issue) : Pagination.
Rastan S, Hough T, Kierman A, Hardisty R, Erven A, Gray IC, Voeling S, Isaacs A, Tsai H, Strivens M, Washbourne R, Thornton C, Greenaway S, Hewitt M, McCormick S, Selley R, Wells C, Tymowska-Lalanne Z, Roby P, Mburu P, Rogers D, Hagan J, Reavill C, Davies K, Glenister P, Fisher EM, Martin J, Vizor L, Bouzyk M, Kelsell D, Guenet JL, Steel KP, Sheardown S, Spurr N, Gray I, Peters J, Nolan PM, Hunter AJ, Brown SD. Towards a mutant map of the mouse--new models of neurological, behavioural, deafness, bone, renal and blood disorders. Genetica. 2004 Sep;122(1):47-9.

Journal article with optional limit to number of authors:
to 3 authors
Name of the first Author, Name of the second author, Name of the third author, et al. Article title. Journal title. Date of publication; Volume (issue) : Pagination.
Rastan S, Hough T, Kierman A, et al. Towards a mutant map of the mouse--new models of neurological, behavioural, deafness, bone, renal and blood disorders. Genetica. 2004 Sep;122 (1):47-9.

or
Name of the first Author, Name of the second author, Name of the third author and others. Article title. Journal title. Date of publication; Volume (issue) : Pagination.

Rastan S, Hough T, Kierman A, and others. Towards a mutant map of the mouse--new models of neurological, behavioural, deafness, bone, renal and blood disorders. Genetica. 2004 Sep; 122(1):47-9.

Journal article with organization as author:
Name of the organization. Article title. Journal title. Date of publication; Volume (issue) : Pagination.
American Diabetes Association. Diabetes update. Nursing. 2003 Nov;Suppl:19-20, 24.

Journal article with organization as author with subsidiary part of the organization included:
Name of the organization, subsidiary part. Article title. Journal title. Date of publication; Volume (issue): Pagination.
American College of Dentists, Board of Regents. The ethics of quackery and fraud in dentistry: a position paper. J Am Coll Dent. 2003;70(3):6-8.

Journal article with multiple organization as author:
Name of the first organization, Name of the second organization, Name of the third organization. Article title. Journal title. Date of publication; Volume (issue) : Pagination.
American Dietetic Association; Dietitians of Canada. Position of the American Dietetic Association and Dietitians of Canada: nutrition and women's health. J Am Diet Assoc. 2004 Jun;104(6):984-1001.

Journal article with both a personal author & organization as author:
Name of the first Author, Name of the second author, Name of the third author; Name of the organization as author. Article title. Journal title. Date of publication; Volume (issue) : Pagination.
Orchard TJ, Temprosa M, Goldberg R, Haffner S, Ratner R, Marcovina S, Fowler S; Diabetes Prevention Program Research Group. The effect of metformin and intensive lifestyle intervention on the metabolic syndrome: the Diabetes Prevention Program randomized trial. Ann Intern Med. 2005 Apr 19;142(8):611-9.

Journal article with personal author & note on the organization as recommended by NISO:

Name of the first Author, Name of the second author, Name of the third author. Article title. Journal title. Date of publication; Volume (issue) : Pagination. Note on the organization.
Orchard TJ, Temprosa M, Goldberg R, Haffner S, Ratner R, Marcovina S, Fowler S. The effect of metformin and intensive lifestyle intervention on the metabolic syndrome: the Diabetes Prevention Program randomized trial. Ann Intern Med. 2005 Apr 19;142(8):611-9. Authors are members of the Diabetes Prevention Program Research Group.

Journal article with no author provided:
Article title. Journal title. Date of publication; Volume (issue) : Pagination.
Pelvic floor exercise can reduce stress incontinence. Health News. 2005 Apr;11(4):11.

Journal article in a language other than English:
Name of the author. [English translation of the article title]. Journal title. Date of publication; Volume (issue) : Pagination.Name of the language.
Berrino F, Gatta G, Crosignani P. [Case-control evaluation of screening efficacy]. Epidemiol Prev. 2004 Nov-Dec;28(6):354-9. Italian.

Journal article published in two equal languages:
Name of the Author.First Article title as present in the text = Second article title as present in the text. Journal title. Date of publication; Volume (issue) : Pagination.Name of the first language, Name of the second language.
Warnock GL. Quality care is job one = Les soins de qualite font du chemin. Can J Surg. 2005 Feb;48(1):6-8. English, French.

Journal article with type of article indicated:
Name of the Authors. Article title [Type of article]. Journal title. Date of publication; Volume (issue) : Pagination.
Zhang Y, Griendling KK, Taylor WR. A critical role for hydrogen peroxide (H2O2) in neointima formation induced by carotid ligation [abstract]. Circulation. 2004 Oct 26;110(17 Suppl):III-259. Abstract no. 1238.
Jackson B, Fleming T. A drug is effective if better than a harmless control [letter]. Nature. 2005 Apr 28;434(7037):1067.
Gayer T, Hahn RW. Regulating mercury: what's at stake? [letter]. Science. 2005 Jul 8;309 (5732):244-5.

Kardel T. [Can a physician pay too many visits? (letter)]. Ugeskr Laeger. 2005 Jun 13;167(24):
2666. Danish.
Flegel K. Biographies of healers [book review]. CMAJ. 2007 Jul 3;177(1):70.

Citing a part of journal article:
Name of the Author. Article title. Journal title. Date of publication; Volume (issue) : Pagination. Name and number of part, title of part; pagination of part.
Diaz-Cruz ES, Shapiro CL, Brueggemeier RW. Cyclooxygenase inhibitors suppress aromatase expression and activity in breast cancer cells. J Clin Endocrinol Metab. 2005 May;90(5): 2563-70. Table 2, Aromatase activity and expression in cell lines; p. 2565.

Citing Newspaper articles:
Standard signed newspaper article:
Author.Article title. Newspaper title (edition). Date of publication; section. Location (column number).
Gaul G. When geography influences treatment options. Washington Post (Maryland Ed.). 2005 Jul 24;Sect. A:12 (col. 1).

Standard unsigned newspaper article:
Article title. Newspaper title (edition). Date of publication; section. Location (column number).
Major decline in U.S. deaths is recorded. New York Times (Washington Final). 2006 Apr 20;Sect. A:14 (col. 6).

Standard newspaper article with optional volume and issue number:
Article title. Newspaper title (edition). Date of publication; Volume(Issue number) section. Location (column number).
Taking steps back to normal after novel rabies therapy. New York Times (National Ed.). 2005 Dec 25;155(53439):23 (col. 3).

Newspaper article in a language other than English:
Article title. Newspaper title (edition). Date of publication; section. Location (column number). Language.

Se retractan cientificos sudcoreanos; admiten mentiras sobre la clonacion. La Jornada (Mexico City). 2006 Jan 5;Sect. A:3 (col. 1). Spanish.

Newspaper article in a language other than English with translated article:
Article title(translated title). Newspaper title (edition). Date of publication; section. Location (column number).
Se retractan cientificos sudcoreanos; admiten mentiras sobre la clonacion [South Korean
scientists retract themselves; they admit lies on cloning]. La Jornada (Mexico City). 2006 Jan 5;Sect. A:3 (col. 1). Spanish.

Newspaper article on the internet:
Author.Article title. Newspaper title (medium). Date of publication; Genre:[size of the article].Available from: url.
Carey B. Psychiatrists revise the book of human troubles. New York Times [Internet]. 2008 Dec 17 [cited 2008 Dec 19];Health:[about 3 p.]. Available from:
http://www.nytimes.com/2008/12/18/health/18psych.html?_r=1&em

Scientific & technical reports:
Standard report written & published by the sponsoring organization:
Author. Title. Place of publication: Publisher; Date of publication. Total number of pages. Report number.
Page E, Harney JM. Health hazard evaluation report. Cincinnati (OH): National Institute for Occupational Safety and Health (US); 2001 Feb. Report No.: HETA2000-0139-2824. 24 p.

Standard report written by performing organization & published by sponsoring organization:
Author(performing organization). Title. Edition. Place of publication: Publisher; Date of publication. Total number of pages. Report number. Contract number.
Sontag ED (Department of Mathematics, Rutgers University, New Brunswick, NJ). Control of nonlinear systems. Final report 15 Mar 2004-31 Jan 2005. Washington: Army Medical Department (US): 2004. 5 p. Report No.: AFRLSRARTR050271. Contract No.: FA95500410172.

Standard report written by performing organization & published by performing organization:

Author. Title. Place of publication: Publisher; Date of publication. Total number of pages. Report number. Contract number. Note.

Popper SW, Wagner CS, Larson EV. New forces at work: industry views critical technologies.Santa Monica (CA): Rand; 1998. 155 p. Report No.: MR-1008-OSTP. Contract No.:OPA-9215205. Supported by the Office of Science and Technology Policy.

Report with author & translator:

Author. Title. Name of the translator,translator. Place of publication: Publisher; Date of publication. Total number of pages. Report number.

Framarin A. First-trimester prenatal screening for Down syndrome and other aneuploidies.Wickens M, translator. Montreal (QC): Agence d'Evaluation des Technologies et des Modes d'Intervention en Sante (CA); c2003. 81 p. Report No.: AETMIS 03-01.

Report with author & editor:

Author. Title. Edition. Name of the editor, editor. Place of publication: Publisher; Date of publication. Total number of pages. Report number.

Rosenbaum, S, Smith BM, Shin P, Zakheim MH, Shaw K, Sonosky CA, Repasch L.Negotiating the new health system: a nationwide study of Medicaid managed care contracts.2nd ed. Johnson K, editor. Washington: George Washington University Medical Center, Center for Health Policy Research; c1998. 2 vols.

Report with editors and translators:

Name of the editor, editor. Title. Name of the translator, translator. Place of publication: Publisher; Date of publication. Pagination.

Pinkau K, Ronn O, editors. Environmental standards: scientific foundations and rational procedures of regulation with emphasis on radiological risk management. Jager G, Kais-Heinrich S, translators. Berlin (Germany): Berlin Academy of Sciences and Technology; 1998.393 p.

Report with organization as author or editor:

Name of the organization.. Title. Place of publication: Publisher; Date of publication. Pagination.

Task Force on Accreditation of Health Professions Education. Strategies for change and improvement: the report of the Task Force on Accreditation of Health Professions Education.San Francisco: University of California, San Francisco, Center for the Health Professions; 1999 Jun. 86 p.

Report in a language other than English:
Author. Title in the original language. Place of publication: Publisher; Date of publication. Total number of pages. Report number. Language.
Contreras A, Drabo Y, Shimp L, de Quinteros P, Linares MA. L'operationnalisation a l'echelle des pratiques familiales cles en matiere de sante et de nutrition de l'enfant: le role du changement des comportements. Washington: Agency for International Development (US); 2004 Apr. 40 p. Report No.: PB2005-104459. French.

Citing a part of reports:
Author. Title. Place of publication: Publisher; Date of publication. Name of the part number of the part, Title of the part; pagination of the part.
Reid PP, Compton WD, Grossman JH, Fanjiang G, editors. Building a better delivery system: a new engineering/health care partnership. Washington: National Academies Press; 2005. Grant No.: 044640. Contract No.: N01-OD-42139. Chapter 3, The tools of systems engineering; p. 27-62.

Websites
Standard citation to a homepage:
Title (type of medium). Place of publication: Publisher; Date of publication(Date of citation). Available from : url
Complementary/Integrative Medicine [Internet]. Houston: University of Texas, M. D.Anderson Cancer Center; c2007 [cited 2007 Feb 21]. Available from: http://www.mdanderson.org/departments/CIMER/.

Homepage with author:
Author. Title (type of medium). Place of publication: Publisher; Date of publication (Date of update; Date of citation). Available from : url
Hooper JF. Psychiatry & the Law: Forensic Psychiatric Resource Page [Internet]. Tuscaloosa (AL): University of Alabama, Department of Psychiatry and neurology; 1999 Jan 1 [updated 2006 Jul 8; cited 2007 Feb 23]. Available from: http://bama.ua.edu/~jhooper/.

Homepage with organization as author:
Organization. Titl(type of medium). Place of publication: Publisher; Date of publication(Date of citation). Available from : url
Gene Ontology Consortium. the Gene Ontology [Internet]. [place unknown]: the Gene Ontology; c1999-2007 [cited 2007 Feb 22]. Available from: http://www.geneontology.org/.

Homepage in a language other than English:
Title[type of medium]. Place of publication: Publisher; Date of publication [date of citation]. Available from : url. Language.
Societe Francaise de Mycologie Medicale [Internet]. Paris: The Society; [2007; cited 2007 Feb 22]. Available from: http://mycolmed.chez-alice.fr/. French.

Citation of a part of websites:
Standard citation of a part of website:
Title of homepage[type of medium]. Place of publication: Publisher; Date of publication of homepage. Title of the part; Date of publication of the part [date of citation of the part]; pagination of the part. The part available from : url
AMA: helping doctors help patients [Internet]. Chicago: American Medical Association; c1995-2007. AMA launches exclusive partnership with the ReachMD Channel for medical professionals; 2007 Mar 26 [cited 2007 Mar 28]; [about 2 screens]. Available from: http://www.ama-assn.org/ama/pub/category/17469.html

Part of a website with name added:
Title of homepage[type of medium]. Place of publication: Publisher; Date of publication of homepage.[name], Title of part Date of Publication of part[date of citation of part]; [pagination of the part]. Part available from: url
fruits & veggies - more matters™ [Internet]. [place unknown]: Produce for Better Health Foundation; c2007. [Chart], Ways to get more; [cited 2007 Mar 27]; [about 3 screens].Available from: http://www.fruitsandveggiesmorematters.org/?page_id=113&iCat=22

Part of a website not in english:

Title of homepage[type of medium]. Place of publication: Publisher; Date of publication of homepage. Title of part; Date of publication of part [date of citation of part]; [pagination of part]. Part available from: url
Senovida [Internet]. [place unknown]: Sociedad Ecuatoriana de Oncologia; [2007]. Que tipos de cancer de mama hay?; [cited 2007 Mar 28]; [about 1 screen]. Available from: http://www.senovida.org/site/info_general/info_02.htm Spanish.

Predatory journals :

Definition : Journals that exploit authors by charging fees without providing legitimate editorial and publishing services, such as rigorous peer review.

Characteristics :

- Lack of editorial or quality control.
- Misleading information about impact factors or indexing.
- Rapid or "guaranteed" publication times.
- Poorly maintained websites, fuzzy images, spelling/grammatical errors.
- Misrepresentation of editorial board identities or reputations.
- Aggressive, indiscriminate email solicitations.

Why are they problematic?

- Undermine scientific credibility and disseminate unvetted information.
- May trick well-meaning researchers, including respected scholars, into publishing substandard or even fraudulent work.
- Publish for profit, not for academic advancement.

Quality journals:

Features :

- Transparent peer-review and editorial processes.
- Clearly stated ethical guidelines.
- Reputable editorial board with verifiable credentials.
- Transparent publication costs and policies.
- Indexed in recognized databases and have verifiable metrics.
- Role in science : Uphold academic integrity, facilitate access to trustworthy research, and support genuine knowledge advancement.

How to distinguish?

- Check for inclusion in recognized databases (e.g., PubMed, Web of Science).
- Review editorial board information and peer-review policies.
- Beware of suspiciously fast publication timelines or unsolicited publishing invitations.
- Use lists and resources (Beall's list, DOAJ) and verify metrics independently.

Computer Programs used in research

The information technology has been helping human beings in various fields and the field of health research is no different in this regard. Various softwares are being designed for simplifying the research and reducing the human effort. The person or the organization performing the research chooses the software depending upon their own requirements. In the following only two softwares used in the research are described.

SPSS:

SPSS is the abbreviation of "Statistical Package for Social Sciences", a software package which is used for statistical editing and analysis. It is widely used by research scholars, scientists, government and private organizations from various social and biomedical sciences. It was first developed by SPSS Inc. and was acquired by International Business Machines (IBM) corp. in 2009 for $1.2 billion. The software is now called as IBM SPSS Statistics.

In 1968, Norman H. Nie, C. Hadlai Hull and Dale H. Bent three pioneers from different professions developed the SPSS with the objective of generating information from data. The generated information will help in taking crucial decisions in various fields. In 1970, first SPSS user manual was published and is still considered as one of the most influential books in sociology. In the later years SPSS evolved into a corporation and grew in strength as the product revolutionalized the global market and social science research. The current version of IBM SPSS Statistics is 24.0 and is available for Windows, Mac OS and Linux.

SPSS can open and write file from different formats such as xlsx (MS Excel), plain text files, ASCII text files, UTF-8,etc and from different databases like MS SQl server, Oracle, SAS, Stata, etc. It can also export files to text, MS Word, MS Excel, HTML, PDF formats, etc.

After opening a file, the data editor window of SPSS always displays two sheets. The first of which displays the data called as data view spread sheet and the second sheet called as variable view spreadsheet explains the variables. This codebook is called as dictionary.

The descriptive statistics calculations including mean, median, mode, variance, standard deviation, etc can be done by selecting descriptive statistics from the menu and then selecting the desired

operation. When this is done a new output window output viewer displays the results.

Apart from performing these operations through opening data editor window and output viewer window the same can be done through syntax editor window by providing the desired commands. But, it is better that the beginners skip these commands and perform the operations through the former method.

SPSS can also easily and quickly generate tables and charts with the data provided. SPSS can also perform various statistical tests like t-test, z-test, chi square test, ANOVA and various multivariate analyses as well.

In the following pages there are screenshots of the data view spreadsheet and variable view spreadsheet from SPSS depicting details of patients from a hospital:

manipulate.sav [DataSet1] - IBM SPSS Statistics Data Editor

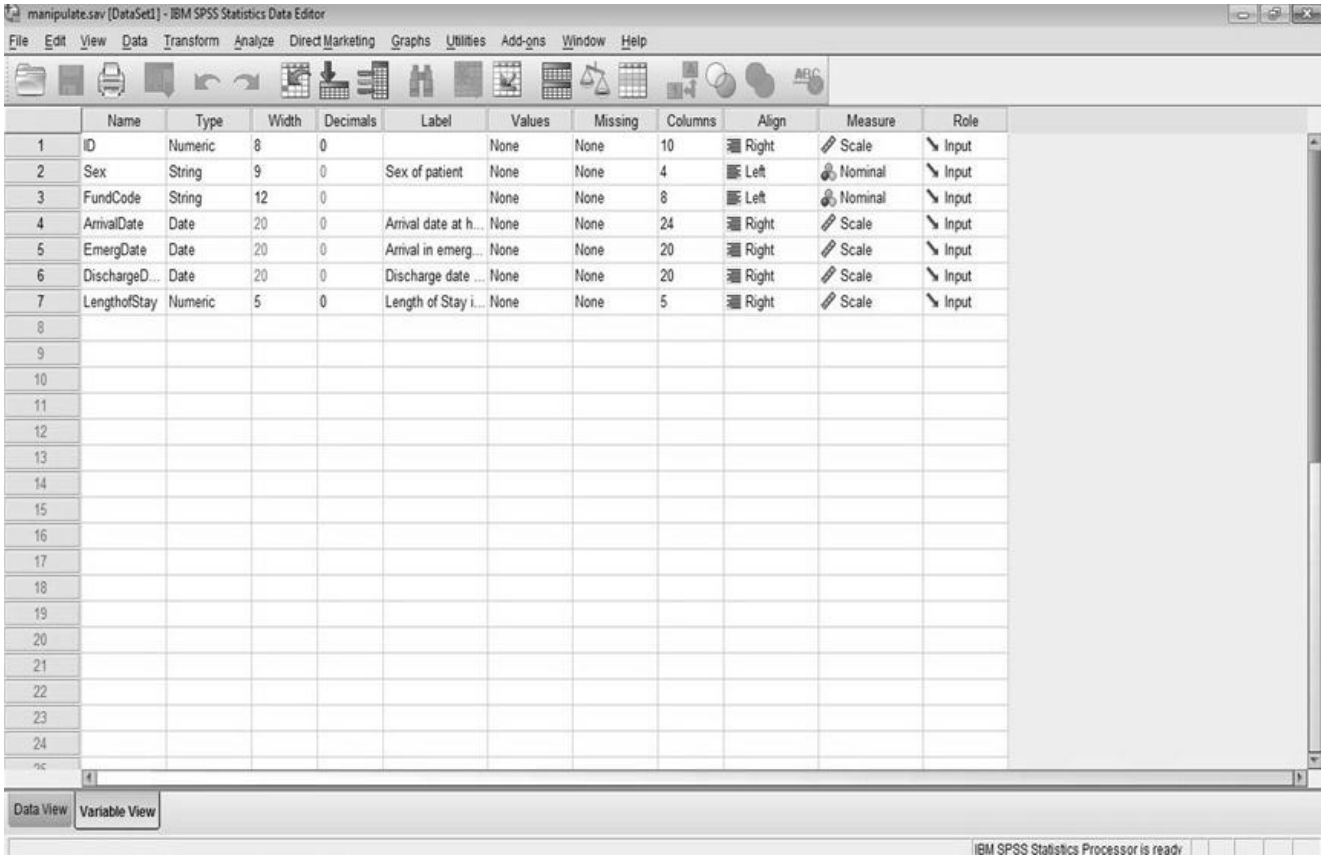
File Edit View Data Transform Analyze Direct Marketing Graphs Utilities Add-ons Window Help

Visible: 7 of 7 Variables

	ID	Sex	FundCode	ArrivalDate	EmergDate	DischargeDate	Lengthof Stay	var	var	var	var	var
1	1	M	HOS	10-Mar-2005 03:04:00	10-Mar-2005 05:09:00	16-Mar-2005 13:00:00	6					
2	2	M	HOS	27-Aug-2004 12:32:00	27-Aug-2004 13:10:00	27-Aug-2004 14:00:00	0					
3	3	M	HOS	19-Feb-2005 19:18:00	20-Feb-2005 03:39:00	25-Feb-2005 01:00:00	5					
4	4	M	TAC	24-Sep-2007 09:35:00	24-Sep-2007 11:38:00	24-Sep-2007 17:05:00	0					
5	5	M	TAC	19-Jan-2009 08:39:00	19-Jan-2009 22:06:00	29-Jan-2009 13:01:00	10					
6	6	F	HOS	16-Dec-2008 18:58:00	17-Dec-2008 18:59:00	2-Jan-2009 05:45:00	16					
7	7	M	HOS	10-Jan-2007 15:00:00	10-Jan-2007 18:22:00	13-Jan-2007 10:00:00	2					
8	8	F	TAC	10-Jun-2009 13:56:00	11-Jun-2009 13:05:00	11-Jun-2009 13:05:00	0					
9	9	M	HOS	13-Jun-2005 15:10:00	13-Jun-2005 22:28:00	18-Jun-2005 16:55:00	5					
10	10	M	HOS	15-Mar-2005 14:22:00	15-Mar-2005 16:53:00	23-Mar-2005 11:56:00	7					
11	11	M	HOS	21-Feb-2007 06:20:00	22-Feb-2007 00:58:00	3-Mar-2007 05:00:00	9					
12	12	M	HOS	28-Dec-2003 07:43:00	28-Dec-2003 09:25:00	31-Dec-2003 11:44:00	3					
13	13	M	HOS	5-Jul-2003 08:13:00	5-Jul-2003 08:25:00	6-Jul-2003 14:45:00	1					
14	14	M	HOS	23-Jul-2003 07:13:00	23-Jul-2003 07:40:00	29-Jul-2003 06:00:00	5					
15	15	F	HOS	31-Jul-2003 05:06:00	31-Jul-2003 09:40:00	9-Aug-2003 03:30:00	8					
16	16	M	HOS	31-Aug-2003 03:54:00	31-Aug-2003 05:20:00	31-Aug-2003 18:45:00	0					
17	17	F	TAC	10-Sep-2003 01:25:00	10-Sep-2003 04:12:00	12-Sep-2003 13:45:00	2					
18	18	M	TAC	23-Sep-2003 22:33:00	23-Sep-2003 23:30:00	24-Sep-2003 04:35:00	0					
19	19	M	HOS	1-Dec-2003 18:49:00	1-Dec-2003 22:19:00	2-Dec-2003 15:50:00	0					
20	20	F	HOS	24-Jan-2004 20:19:00	25-Jan-2004 02:58:00	28-Jan-2004 20:35:00	4					
21	21	M	HOS	8-Jun-2004 20:45:00	8-Jun-2004 23:26:00	12-Jun-2004 11:05:00	3					
22	22	M	HOS	14-Jun-2004 01:32:00	14-Jun-2004 04:29:00	16-Jun-2004 15:00:00	2					

Data View | Variable View

IBM SPSS Statistics Processor is ready


manipulate.sav [DataSet1] - IBM SPSS Statistics Data Editor
File Edit View Data Transform Analyze Direct Marketing Graphs Utilities Add-ons Window Help
Data View
Variable View
IBM SPSS Statistics Processor is ready

	Name	Type	Width	Decimals	Label	Values	Missing	Columns	Align	Measure	Role
1	ID	Numeric	8	0		None	None	10	Right	Scale	Input
2	Sex	String	9	0	Sex of patient	None	None	4	Left	Nominal	Input
3	FundCode	String	12	0		None	None	8	Left	Nominal	Input
4	ArrivalDate	Date	20	0	Arrival date at h...	None	None	24	Right	Scale	Input
5	EmergDate	Date	20	0	Arrival in emerg...	None	None	20	Right	Scale	Input
6	DischargeD...	Date	20	0	Discharge date ...	None	None	20	Right	Scale	Input
7	LengthofStay	Numeric	5	0	Length of Stay i...	None	None	5	Right	Scale	Input
8											
9											
10											
11											
12											
13											
14											
15											
16											
17											
18											
19											
20											
21											
22											
23											
24											

Minitab:

Minitab is a statistical software widely used for statistical analysis by researcher and scientists. It was developed by Pennsylvania state university researchers namely Barbra F. Ryan, Thomas A. Ryan, Brian L. Joiner in the year 1972. It was launched as OMNITAB, a statistical analysis program which was a lighter version. It is distributed by Minitab Inc., a private company with its headquarters located in state college, Pennsylvania.

Minitab is the first e-learning package with a statistical tool. It helps in carrying out various numerical and graphical analysis. Being an interactive program when Minitab is supplied with data input it responds to the respective command instantaneously by computing the supplied data. Minitab provides the facility of running a group of commands in a batch program. In this way several commands can be executed in a sequence and the output is presented to the user. Thus it provides varied functions from preparing data for analysis to converting data into solutions.

Data input and output: the input of data into mintab can be made from a variety of files (MS-Word, MS-Excel,etc). The program provides the features such as “smart data import” which can also correct mismatches apart from importing the file.

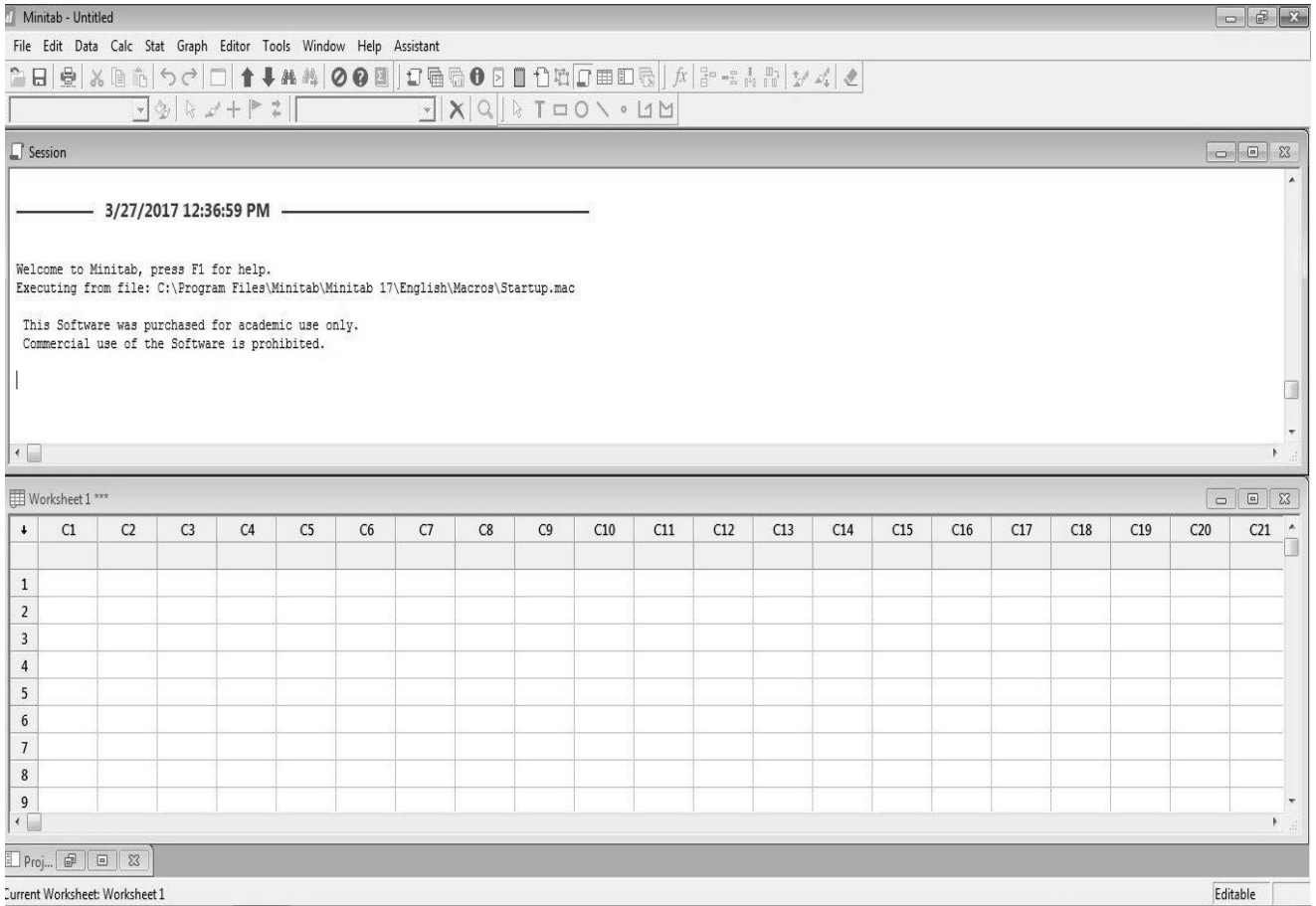
Minitab can provide output to a variety of files. Every file is given a file name with an extension indicating the file type. For example, in “prevalence.mtw” the word prevalence indicates the name of the file type and “mtw” is the extension indicating that it is mintab worksheet.

Graphing data: The data can be summarized using different graph options provided in Minitab menu option “Graph”. These commands produce good quality graphs.

Statistical analysis:

With the help of minitab many descriptive and inferential statistical analysis can be performed conveniently. Parametric tests including t-test, ANOVA , linera regressions, etc. and non-parametric tests such as Mann-Whitney test, Wilcoxon signed rank test, Kruskal Wallis test, Chi-square test, etc can be performed.

In the following page there is a screenshot from the minitab software:


Minitab - Untitled
File Edit Data Calc Stat Graph Editor Tools Window Help Assistant
Session
3/27/2017 12:36:59 PM
Welcome to Minitab, press F1 for help.
Executing from file: C:\Program Files\Minitab\Minitab 17\English\Macros\Startup.mac
This Software was purchased for academic use only.
Commercial use of the Software is prohibited.
Worksheet 1 ***
C1 C2 C3 C4 C5 C6 C7 C8 C9 C10 C11 C12 C13 C14 C15 C16 C17 C18 C19 C20 C21
1 2 3 4 5 6 7 8 9
Proj...
Current Worksheet: Worksheet 1
Editable